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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

In re CONNETICS SECURITIES LITIGATION.	Case No. C 07-02940 SI **SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** CLASS ACTION DEMAND FOR JURY TRIAL

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Court-appointed Lead Plaintiff, the Teachers' Retirement System of Oklahoma ("Oklahoma Teachers" or "Lead Plaintiff"), brings this federal securities law class action on behalf of itself and all other persons and entities, other than Defendants and their affiliates, as specified below, who purchased or acquired the securities of Connetics Corp. (n/k/a Steiffel Laboratories, Inc.) ("Connetics" or the "Company") between January 27, 2004 and July 9, 2006 (the "Class Period"), and were damaged by the conduct asserted herein.

I. INTRODUCTION

1. Connetics was a specialty pharmaceutical company that developed and marketed products for the medical dermatology market. Connetics' primary business was the development and marketing of dermatological products designed to treat skin conditions such as psoriasis, seborrheic dermatitis and acne.

2. During the Class Period, Connetics and its senior executives told investors that the Company was developing a revolutionary new acne medication for future sale in the United States, while at the same time experiencing strong sales and revenues from its existing products. As Defendants knew, however, the acne medication had failed an important pre-clinical safety test and stood virtually no chance of being approved by the United States Food and Drug Administration ("FDA") within the time frame that Defendants represented to investors. Defendants also knew that the Company's publicly reported financial results materially overstated the Company's revenues and profits in violation of Generally Accepted Accounting Principles ("GAAP").

3. Connetics' new topical treatment for acne was called Velac Gel ("Velac"). According to Defendants, Velac was a ground-breaking product that would allow Connetics to capture a large part of the lucrative prescription acne market – the largest segment of the dermatology market and worth approximately $1.6 billion in annual sales. Indeed, the Defendants repeatedly promoted Velac, stating it has the "potential to become our biggest selling product" and it "will become the topical treatment of choice for inflammatory and noninflammatory acne."

4. Velac was a purported breakthrough in the treatment of acne. Previously, no drug

had successfully combined the "active" ingredients in Velac, clindamycin and tretinoin. Normally, tretinoin and clindamcyin are incompatible agents; tretinoin will cause clindamycin to breakdown. Velac, however, utilized a new "vehicle" (sometimes referred to as an aqueous hydrogel) that prevented the breakdown of clindamycin. The new vehicle was critically important to the development of Velac.

5. Defendants initially represented that the Company was likely to obtain approval of Velac no later than the third quarter of 2005 (3Q05) and later asserted that approval was likely no later than June 25, 2005, when the FDA was required to issue a decision on the Company's Velac application pursuant to the Prescription Drug User Fee Act ("PDUFA"). For example, during a conference call on January 25, 2005, Defendant Higgins stated with regard to "Velac, we expect to be launched midyear." And, on the same conference call, Defendant Vontz stated with regard to Velac:

> **[W]e know a lot about our product** and . . . **we're very confident in the data set that we've got.** We believe it's **one of the strongest data sets for an acne product submitted to the FDA**. And we're obviously **very excited to launch it**.
>
> * * *
>
> I have a lot of confidence in the strength of our data.[1]

6. Analysts covering the Company followed and reported on Defendants' statements about Velac. They referred to Velac as a "unique" product and a "fundamental catalyst" for the Company's future growth. No later than June 2004, the market expected Velac to bring in tens of millions of dollars in revenue for Connetics starting in fiscal year 2005 and for Velac to become the Company's best-selling product by fiscal year 2007.

7. The Defendants did not tell the market, however, that Velac had failed a critical pre-clinical safety test. Specifically, from January 2004 through June 2004, while Connetics was aggressively promoting Velac to the market, the Company was also conducting a laboratory study on Velac known as a Tg.AC mouse dermal carcinogenicity study (the "Mouse Study"). This Mouse Study, required by the FDA, was designed to determine whether Velac was safe for

[1] All emphasis has been added unless otherwise noted.

long-term use and, in particular, whether it had any carcinogenic effects. In mid-June 2004, Connetics received the results of the study and learned that **89 out of 160 (approximately 56%)** mice treated with Velac had developed cancerous skin tumors.

8. On June 28, 2004, unbeknownst to investors, Connetics internally convened a panel of toxicology experts to provide feedback on the results of the study. The panel consisted of Claudio Conti, DVM, Ph.D., University of Texas, M.D. Anderson Cancer Center; Ronald E. Cannon, Ph.D., National Institute of Environmental Health Sciences; Dana Dunn, formerly of Milestone Biomedical Associates; Peter Mann, DVM, EPL Northeast; R. Michael McClain, Ph.D., McClain Associates; Fred Reno, Ph.D., Toxicology Consultant; David B. Clissold, Hyman, Phelps & McNamara, P.C.; Judson Spalding, Ph.D.; Hilary V. Sheevers, Ph.D., Milestone Biomedical Associates; and Martin L. Wenk, Ph.D., DABT, BioReliance Corporation. At that meeting, the expert toxicologists told Connetics that the panel did not know of any drug that exhibited a "positive dermal" similar to Velac that ever had been approved by the FDA. Each expert panelist was required to sign a confidentiality agreement; Defendants took steps to make sure this information did not become known to the public during the Class Period.

9. According to one of the members of the expert panel convened by Connetics on June 28, 2004 (*see* description of Confidential Witness 5 ("CW5"), *infra.* at ¶43(e)), if a drug is tested on Tg.AC mice and the mice develop tumors, it at least means that further testing needs to be done. According to CW5, the FDA would **not** approve a drug that had positive results in the Tg.AC study without further testing demonstrating that the drug is not tumorigenic. Moreover, according to CW5, it is not unusual for 0.5% or 1% of the control group to develop tumors. Therefore, if the drug shows 2-3% tumor development, the finding may not be significant. If you are testing 100-200 animals, and 20% develop tumors, that is clearly significant.

10. Accordingly, at least as early as June 28, 2004, Defendants knew the Company would not be able to obtain FDA approval of Velac by the PDUFA date or anytime within the time frame Defendants communicated to investors. To perform another animal test would push back any possible approval of Velac by at least six months, if not years. According to Connetics former Director of Pharmacology and Toxicology (*see* description of CW1, *infra* at ¶43(a)),

animal testing of Velac would take between 10 months to 3 years. And, according to the Company's former Senior Manager of Regulatory Affairs (whose job was to act at the Company's liaison with the FDA) (*see* description of CW6, *infra* at ¶43(f)), once the Company knew the results of the Mouse Study the only way it could get Velac approved would be to perform a two-year CARC study.

11. According to a former Connetics employee (*see* description of CW4, *infra* at ¶43(d)), he knew from his attendance at an internal presentation by the Company's Director of Pharmacology and Toxicology that there were clear signs prior to April 2005 that the Company would have problems getting Velac approved by the FDA. That meeting occurred in late 2003 or early 2004 and was attended by Defendants Vontz, Higgins and Wiggans.

12. Rather than disclose to investors that Velac had tested positive in a Tg.AC mouse carcinogenicity test, the Defendants concealed the results of the Mouse Study from the market and actively misled investors as to Velac's prospects for FDA approval. They continued to issue public statements referring to Velac as "safe and well tolerated" in documents publicly-filed with the United States Securities and Exchange Commission ("SEC"), submitted a new drug application for Velac to the FDA, told investors that they expected FDA approval by the PDUFA date of June 25, 2005, and included revenue from Velac in guidance for 2005.

13. Analysts continued to believe Defendants' false statements. For instance, on March 30, 2005 one analyst wrote: "We recently spent a day meeting with Connetics' Executive Vice President and CFO, John Higgins. . . . For Velac, the Company and we remain confident that this represents a peak sales opportunity of $150 million or greater and **the Company has high confidence in an outright FDA approval by June 25th 2005**."

14. On April 13, 2005, Connetics held a conference call with the FDA to discuss the FDA's comments on the new drug application for Velac. During that call, the FDA repeated the information that Connetics' own toxicology experts had told the Company on June 28, 2004 – namely, that the carcinogenic result of the Tg.AC Mouse Study was a serious impediment for the approval of Velac for sale in the United States. Indeed, according to a Connetics former Senior Manager of Regulator Affairs who was the Company's liaison with the FDA and who attended

the April 13, 2005 conference call (CW6), the FDA made it clear that approval may be a problem.

15. On April 14, 2005, the day after being told by the FDA that Velac "may be a tumor promoter or a carcinogen" and that "this is a serious issue," Defendant Wiggans and the Connetics senior management hosted Connetics' 2005 Analyst and Investor Day in New York City. Analysts who attended the Company's presentations repeated the false and misleading statements made during the Conference, noting Connetics "appears to be confident in approval" of Velac and the "Company is positioned on the verge of launching its first potential $100 MM therapeutic, Velac, with FDA approval anticipated mid-year."

16. Defendants did not disclose any aspect of the FDA's comments to the public until April 26, 2005. During that time, two of the Defendants named below (including Connetics' Vice President of Biostatics and Clinical Operations) began selling their holdings of Connetics' stock and executing short-selling transactions based on their insider knowledge. On April 26, 2005, Connetics issued a press release **partially** disclosing limited aspects of the issues raised by the FDA. This press release stopped short, however, of revealing the major issues surrounding Velac and falsely stated that Connetics had been told by its experts that the carcinogenic results of the Mouse Study were the result of a limitation of the test, which analysts understood to mean that the Mouse Study results were not likely to impede obtaining FDA approval. In addition, Defendants misled investors by assuring them the Company still believed it could obtain FDA approval by the PDUFA date by providing the FDA additional information.

17. On June 13, 2005, Connetics disclosed that it had received a "non-approvable" letter from the FDA regarding Velac. In that press release, Connetics stated that "the only issue raised in the non-approvable letter was a positive carcinogenicity signal that was detected in a Tg.AC mouse dermal carcinogenicity study." In other words, the FDA had refused to approve Velac based on the results of a study that the Defendants had known of (but hid from the market) for **nearly a year**. The price of Connetics' stock collapsed on this news, dropping almost 27 percent on heavy volume.

18. Even after the June 13, 2005 announcement, however, the market did not know

the full extent of the cover-up surrounding Velac. This information was not revealed until nearly a year later when the SEC filed a civil complaint in the Southern District of New York against Defendants Alexander J. Yaroshinsky and Victor E. Zak for insider trading based on their advance knowledge of the FDA's concerns about Velac.

19. In addition to concealing known problems with the development of Velac, the Insider Defendants also caused Connetics to issue false and misleading financial statements throughout the Class Period. As discussed below, Lead Plaintiff's investigation has revealed that during the Class Period, Connetics systematically inflated its sales and revenue by intentionally shipping more of its products to distributors than the retail marketplace demanded or would need in the foreseeable future. This practice defrauded investors in at least two ways: (i) the Company improperly booked sales in the near-term at the expense of future periods, which distorted the true state of the company's finances and likely future sales; and (ii) because these sales were subject to a right of return, and Defendants knew that all the excess inventory being held by the distributors would have to be returned if it expired, the Company was required to take large reserves to account for these potential returns and/or substantial portions of the shipments should not have qualified as sales at all. Thus, these knowingly improper shipments caused the Company's financial statements to be materially false and misleading in violation of GAAP.

20. As a direct result of selling product to distributors in excess of retail demand and not properly booking reserves for those sales, Connetics was eventually forced to restate its financial statements, thus admitting that they were in violation of GAAP throughout the Class Period. Moreover, Connetics has admitted that the restatement was "due to errors in the accounting" for accruals for rebates, chargebacks and returns. By restating due to "errors" in its financial statements, Connetics has admitted that the Company's financial statements were materially false and misleading at the time they were filed with the SEC, and that the Company had in its possession (but chose to ignore) the necessary information to make truthful disclosures at the time it filed its financial statements. In addition, Connetics admitted in the restatement that it suffered from material weaknesses in its internal controls over financial reporting during the Class Period – despite the fact that the Company's senior executive officers repeatedly signed

sworn certifications attesting to the adequacy of those controls.

21. The GAAP violations were not the result of ignorance or negligence. The Company's SEC filings, signed by Wiggans and Higgins, represented to investors: "We monitor wholesaler inventory using a combination of techniques, including evaluating how much inventory is sold through to the wholesalers' customers, which we do by tracking the prescriptions filled for our products at the pharmacy level. . . ." And, the Company's SEC filings further assured investors that Connetics' "senior management has reviewed these critical accounting policies and related disclosures." Moreover, Defendants assured investors during the Class Period that the Company was "monitoring the shelf life of existing product as it moves through the distribution channel going forward." According to Defendants' statements in SEC filings, the Company contractually prevented distributors from purchasing excess product, and Connetics monitored and maintained the amount of product being sold to the Company's distributors so as to prevent the buildup of excess inventory. Further, when inventory issues arose in December 2005, Connetics entered into amended distribution agreements with two of its three main distributors, agreeing to "jointly use best efforts to adjust inventory levels . . . to accurately reflect Product demand." Both amendments were signed by Defendant Higgans.

22. While Defendants claimed to be monitoring distributors' inventory levels and preventing buildup of excess product, according to former Connetics employees, the Insider Defendants caused the Company to ship excess product to distributors so the Company could artificially inflate its reported earnings and revenues. For instance, according to a former National Account Director in charge of Sales Operations (CW3), Defendants shipped product to distributors to meet analyst expectations and not because distributors needed the product. As a result, according to this former National Account Director, "the numbers have never been real from day one" and the Company was "not honest with the public." Similarly, according to a former Regional Sales Director (CW10) there was always "way too much" inventory at distributors. A former Senior Vice President of Sales (CW7) and a Territory Manager (CW11), among others, also confirmed the Company regularly shipped more product than distributors needed causing excess product build up.

23. The Company ultimately was forced to restate its earnings primarily, but not exclusively, because the Company had improperly recorded reserves for sales to the Company's distributors. As this product began to expire, Connetics abrupbtly had to stop shipments to its distributors toward the end of the Class Period to reduce the inventory levels at distributors and to prevent distributors from returning product for substantial refunds in excess of the initial sales price.

24. According to former employees, including a former National Account Director in charge of Sales Operations (CW3), and the Company's SEC filings, Connetics regularly increased the prices of the drugs it sold to distributors. Connetics' return policy, however, guaranteed distributors the right to return expired or expiring product for a credit at the **then-current** sales price less 5%. Refunds were **not** calculated based on the initial sales price for a drug. For example, if Connetics sold an order of Soriatane to its distributor McKesson at a price of $1 million and then two years later McKesson needed to return the product because it was close to expiration – and the price of Soriatane had increased 50% over that two year period – Connetics would have to pay McKesson $1.425 million. As a result, Connetics could actually **lose** money on certain of Defendants' improper shipments of excess product to the Company's distributors.

25. Yet, despite the fact that Defendants knew Connetics' distributors had excess inventory, and that the Company's drug prices had appreciated significantly in each year during the Class Period, Defendants did not properly account for these likely returns. Indeed, the Company's restatement admits:

> **[W]e calculated the value of the estimated units to be returned using the original sales price without taking into account price increases that were implemented between the date of sale through the period of the accrual**. We permit wholesalers to return expired or expiring product for a credit at the then-current sales price less 5%, so the initial sales price may not fully capture our liability for future returns. As a result of our evaluation, we determined that our accrual for product returns had been understated and concluded that the impact of the errors required us to restate our financial statements for prior years.

26. In addition, the Company admitted the restatement was necessary because the Company had failed to consider "all units with potential risk of return" in calculating returns

accruals. The Company's restatement covers the three full years 2003-2005 covered in Lead Plaintiff's case.

27. As a result of the truth about Connetics being disclosed to investors, ending with the Company's disclosure on July 10, 2006, the price of Connetics' common stock, which traded as high as $29 per share immediately before the first partial disclosure of the issues with Velac, plunged to $7.76, resulting in a loss of hundreds of millions of dollars in market capitalization.

II. JURISDICTION AND VENUE

28. Certain claims asserted herein arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), 78t(a) and 78t-1, and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b-5").

29. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1331, because this is a civil action arising under the laws of the United States.

30. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

31. In connection with the acts alleged in the Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mails, interstate telephone communications and the facilities of national securities exchanges.

III. THE PARTIES

A. Lead Plaintiff

32. Lead Plaintiff Oklahoma Teachers is a government-sponsored retirement plan that manages approximately $8 billion dollars in assets, and is headquartered in Oklahoma City, Oklahoma. Founded in 1943, Oklahoma Teachers provides retirement, disability and survivor benefits to thousands of employees of Oklahoma public schools and other state-supported educational institutions. During the Class Period, Oklahoma Teachers purchased common stock in Connetics. As a result of these purchases and the violation of the securities laws alleged

herein, Oklahoma Teachers suffered substantial damages. On December 14, 2006, the court in the United States District Court for the Southern District of New York, the Honorable Judge Shirley Wohl Kram presiding, appointed Oklahoma Teachers as Lead Plaintiff in this litigation for all claims and causes of action raised herein. [2]

B. Defendants

1. The Company

33. Connetics was incorporated in 1993 as a Delaware corporation. Throughout the Class Period, Connetics operated as a pharmaceutical company specializing in the development, production, and distribution of dermatological products principally throughout North America. Connetics was listed on the NASDAQ exchange during the Class Period, where its stock was publicly traded under the symbol "CNCT."

2. The Insider Defendants

34. Defendant Thomas G. Wiggans ("Wiggans") was Connetics' Chief Executive Officer and a director throughout the Class Period. He also served as President of Connetics from July 1994 to February 2005. He was appointed Chairman of the Board of Directors in January 2006. Wiggans signed each of Connetics' Form 10-Ks and 10-Qs that were publicly-filed with the SEC during the Class Period, as well as the registration statement for Connectics' publicly issued bonds. Pursuant to Sections 302 and 906 of the Sarbanes Oxley Act of 2002 ("Sarbanes Oxley"), Wiggans certified the accuracy of Connetics' Form 10-Ks and 10-Qs and the accuracy and effectiveness of Connetics' financial disclosures and internal controls over financial reporting. Throughout the Class Period, Wiggans also participated in numerous conference calls with analysts and investors.

35. Defendant Gregory Vontz ("Vontz") began serving as Connetics' Executive Vice President and Chief Commercial Officer in December 2001. He was appointed Chief Operating

[2] To preserve its right to appeal certain rulings set forth in the Order Granting Defendants' Motion to Dismiss and Defendants' Motion to Strike, Lead Plaintiff hereby re-alleges the claims alleged in the Amended Consolidated Class Action Complaint for Violations of the Federal Securities Laws. *See Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1474 (9th Cir. 1997).

Officer in January 2001 and promoted to President in February 2005. Throughout the Class Period, Vontz participated in numerous conference calls with analysts and investors.

36. Defendant John Higgins ("Higgins") joined Connetics in 1997 as Chief Financial Officer. He then served as Connetics' Vice President, Finance and Administration from September 1997 through December 1999. From January 2000 to December 2001, Higgins served as Executive Vice President, Finance and Administration. From January 2002 through the end of the Class Period, Higgins served as the Executive Vice President, Finance and Administration and Corporate Development. Higgins signed Connetics' Form 10-Ks that were publicly-filed with the SEC on or about March 16, 2005 and March 13, 2006 and each of the Form 10-Qs that were publicly-filed with the SEC during the Class Period, as well as the registration statement for Connetics' publicly issued bonds. Pursuant to Sections 302 and 906 of Sarbanes Oxley, Higgins certified the accuracy of Connetics' Form 10-Ks and 10-Qs and the accuracy and effectiveness of Connetics' financial disclosures and internal controls over financial reporting. Throughout the Class Period, Higgins also participated in numerous conference calls with analysts and investors.

37. Defendant Lincoln Krochmal ("Krochmal") joined Connetics in October 2003 as Executive Vice President of Research and Product Development. Krochmal was directly involved in preparing regulatory submissions and conducting FDA-required tests relating to Velac. Throughout the Class Period, Krochmal participated in numerous conference calls with analysts and investors. The vast majority of Krochmal's shares owned during the Class Period were in the form of unexcercisable stock options that did not vest until May 23, 2006, and were "underwater" during all or part of the Class Period.

38. Defendants Wiggans, Higgins, Vontz and Krochmal were members of Connetics' Management Executive Committee, which was responsible for "the overall direction, strategy and operations of Connetics, including, among other things, corporate financial performance, commercial performance, research, development and product operations performance." (2006 Schedule 14A Proxy at 11.)

39. Defendants Wiggans, Higgins, Vontz and Krochmal are collectively referred to herein as the "Insider Defendants."

3. Defendant Alexander J. Yaroshinsky

40. Defendant Alexander J. Yaroshinsky ("Yaroshinsky") served as Vice President of Biostatics and Clinical Operations for Connetics during the Class Period. As a senior member of Connetics' research and product development team, Yaroshinsky's duties included designing and conducting drug development studies, analyzing the results of those studies and preparing regulatory submissions to the FDA. In order to carry out his responsibilities at Connetics, Yaroshinsky was entrusted with non-public information concerning the approval process of Connetics' developmental stage drugs. As described below in ¶¶44-55, Yaroshinsky is a named defendant in an amended complaint dated June 20, 2006, that was filed by the SEC in the United States District Court for the Southern District of New York, captioned *United States Securities and Exchange Commission v. Alexander J. Yaroshinsky, et al.*, 06-CV-2401-CM (the "SEC Complaint").

4. Defendant Victor E. Zak

41. Defendant Victor E. Zak ("Zak") is a named Co-defendant with Defendant Yaroshinsky in the SEC Complaint. Zak is a resident of Newton, Massachusetts. On or about April 13, 2005, Zak received a telephone call from Yaroshinsky at Zak's office in Connecticut, during which Yaroshinsky conveyed to Zak material, non-public information regarding the approvability and safety issues with Velac. Defendant Zak used this material, non-public information to execute numerous transactions in Connetics securities. Zak unlawfully profited from insider trading during the Class Period by more than $900,000.

IV. LEAD PLAINTIFF'S INVESTIGATION

42. The allegations contained herein are based upon information and belief with information obtained through the investigation made by and through Lead Counsel. Lead Counsel's investigation has included, among other things: (i) interviews of former employees of Connetics and other percipient witnesses with first hand knowledge of the events alleged herein; (ii) a review of filings by Connetics with the SEC, Company press releases and statements, and

Company conference call transcripts in which the Company has admitted its financial statements released during the Class Period were false and misleading and that Velac received a positive response as a carcinogen in a Tg.AC mouse study that was performed by Connetics prior to the submission of its NDA, the results of which the Company analyzed with a panel of experts; (iii) a review of court filings in the action styled *United States Securities and Exchange Commission v. Alexander J. Yaroshinsky, et al.*, 06-CV-2401-CM, including sworn statements and Yaroshinsky's admissions therein; (iv) media and analyst research reports; (v) consultation with experts; (vi) consultation with the Company that conducted much of the early validation work that led to the FDA's acceptance of the Tg.AC mouse model, BioReliance Corporation; and, (vii) review of literature concerning the Tg.AC mouse study. Moreover, the investigation included contacts with organizations and individuals from whom information presently is unavailable because the witnesses are unable or unwilling to cooperate, including contacts with attorneys for the SEC concerning the investigation into the Company, a January 5, 2007 request of records from the Food and Drug Administration pursuant to the Freedom of Information Act, 5 U.S.C. §552, and members of the Company's panel of experts convened on June 28, 2004, who cite confidentiality agreements.

A. The Allegations Are Supported By The Accounts of Confidential Witnesses

43. The allegations herein are supported in part by first-hand accounts of 12 Confidential Witnesses, including former Connetics employees and consultants. The Confidential Witnesses have been identified with particularity but without disclosing identities in order to address concerns about retaliation or career injury:

(a) Confidential Witness 1 ("CW1") was a Former Director of Pharmacology and Toxicology from August 1999 to June 1, 2004 who reported to Defendant Vontz. CW1 ran some of the pre-clinical studies for Velac. As alleged in further detail at ¶88, before Connetics chose a model for conducting its pre-clinical testing, CW1 met with Connetics' Product Development Review Committee (the "PDRC"), which included, among others, Defendants Higgins, Wiggans and Vontz. At this meeting, CW1 explained the various models and the risks involved. CW1 explained that Connetics could conduct a transgenic mice study, in which the

mice have a gene mutation that makes them more sensitive for tumor growth, or they could use a traditional method with normal mice. The transgenic mice study would only take ten months to complete whereas the traditional method would require three years. According to CW1, the Committee decided to use the transgenic mice model because time was critical and, in the pharmaceutical industry, there is always pressure to get the drug out before another company does. According to CW1, the Mouse Study began in the second half of 2003 or early 2004 and was conducted at an outside toxicology lab in Washington.

(b) Confidential Witness 2 ("CW2") is an employee of BioReliance Corporation. According to filings in the SEC action against Yaroshinsky attended the meeting of Connetics' June 28, 2004 expert panel. CW2 confirms that BioReliance conducted the Mouse Study testing for Connetics and that BioReliance filed a report with Connetics regarding the data and the testing of that material.

(c) Confidential Witness 3 ("CW3") was a former National Account Director in charge of Sales Operations who worked at Connetics for more than eight years and throughout the entire Class Period and who knew Defendant Yaroshinsky well. As alleged in further detail at ¶90, according to CW3, Defendants Yaroshinsky, Vontz and Krochmal were directly in charge of overseeing the pre-clinical testing of Velac and were involved in every step of the developmental process for the drug, including oversight of the Mouse Study. Throughout the Class Period, Yaroshinsky reported directly to Vontz and Krochmal and provided regular updates on the Velac regulatory process to certain members of the Management Executive Committee, including Wiggans and Higgins.

As alleged in further detail at ¶¶166-172, 174, according to CW3, the Company's announcement that it had to restate was not a surprise to anyone in the Company because "the numbers have never been real from day one" and the Company was "not honest with the public." CW3 explained, the amount of product Connetics shipped to wholesalers consistently did not match the demand for the product. During the last two weeks of a quarter Wiggans, Higgins and Vontz would cause Connetics to ship significant amounts of additional and unnecessary inventory for the sole purpose of meeting or exceeding Wall Street's expectations for the Company's sales

and revenue for that period. According to CW3, the Company "always met its Wall Street numbers," but never meet its internal goals for prescriptions written. Also according to CW3, Defendants Wiggans and Vontz were repeatedly told during the Class Period that the amounts of product being shipped greatly exceeded the known data about the number of prescriptions written, but Wiggans and Vontz purportedly did not want to hear about it. According to CW3, distributors agreed to take excess product from Connetics because the Company's prices for drugs were increasing by as much as 15-18% twice a year and distributors wanted to be able to buy at the lower price and then pass on the price increase to pharmacies.

(d) Confidential Witness 4 ("CW4") was an employee of Connetics' Strategic Market Planning group who was employed at Connetics from 2002 through April 2006. CW4 initially focused on long range planning and forecasting, then moved to focusing on sales. As alleged in further detail at ¶91, CW4 served as the commercial representative for Velac and was kept informed as to its progress towards approval for commercial sale. Moreover, CW4 was friends with Defendant Yaroshinksy. According to CW4, there were clear signs before April 2005 that the Company would have problems getting Velac approved by the FDA. For instance, according to CW4, in late 2003 or 2004, CW4 attended an Executive Committee Meeting that was also attended by Jay Finister (Senior VP of Marketing), Danine Summers (VP of Marketing), Dr. Xinfan Huang (Director of Pharmacology and Toxicology and lead pre-clinical scientist for the Mouse Study), Defendant Vontz, Defendant Higgins, Defendant Wiggans and others. According to CW4, Dr. Huang gave a presentation at the meeting concerning the Mouse Study and it was clear that there were high incidences of tumors in the mice in the study. During this meeting, the attendees discussed how to "risk mitigate" the findings of the Mouse Study.

As alleged in further detail at ¶¶169-170, CW4 was directly involved in the forecasting process for more than three years (including throughout the Class Period) and would assist in the preparation of the Company's initial annual forecasts and present them to, among others, Defendants Wiggans, Higgins and Vontz in October of each year. Wiggans instructed CW4 throughout the Class Period to increase the forecasts so that they were in line with Wall Street's expectations for Connetics' future sales. For instance, in the presence of Higgins and Vontz,

Wiggans scolded CW4 for presenting an initial forecast for 2005 that was below Wall Street's expectations, and Wiggans instructed him to increase the forecast. This happened a lot; employees kept "CYA" folders to document such activities. For instance, according to CW4, one employee, who told CW4 that he was not comfortable with what the Company was doing and was considering being a "whistle blower" to the SEC, maintained a "CYA" file that contained ninety-three different iterations of the forecast he was required to make in one year.

(e) Confidential Witness 5 ("CW5") was one of the experts on Connetics panel that was convened on June 28, 2004. CW5 attended two meetings, one in Washington regarding the toxicology of a drug. CW5 attended the June 28, 2004 meeting. CW5 believes that he is subject to a confidentiality agreement preventing disclosure, particularly as to technical information about the level of toxicity of the drug. As to the Tg.AC model, CW5 confirms that if a drug is tested on Tg.AC mice and the mice develop tumors, it at least means that further testing needs to be done. According to CW5, the FDA would not approve a drug that had positive results in the Tg.AC study without further testing. Moreover, according to CW5, it is not unusual for 0.5% or 1% of the control group to develop tumors. Therefore, if the drug shows 2-3% tumor development, the finding may not be significant. According to CW5, if you are testing 100-200 animals and 20% develop tumors, it would be considered significant.

(f) Confidential Witness 6 ("CW6") was a former Connetics Senior Manager of Regulatory Affairs from October 2001 to February 2007, whose job it was to handle dealings with the FDA, and would give strategic and regulatory advice on projects under development. As alleged in further detail at ¶¶98, 100, 107-108, CW6 attended the Company's meeting with the FDA on April 13, 2005. CW6 had not previously worked on Velac but attended the meeting because the Company's usual liaison with the FDA could not make it. According to CW6, the FDA told Connetics that the Mouse Study results "may be a problem." According to CW6, during the meeting, Connetics argued with the FDA's interpretation of the data but that it did not look good for obtaining approval of Velac. Moreover, according to CW6, once the Company learned the results of the Tg.AC Mouse Study there was nothing the Company could do to prove that Velac was safe other than to conduct a two-year CARC study.

(g) Confidential Witness 7 ("CW7") is a former Senior Vice President in the sales department who worked at the Company for nearly three years before leaving in late 2005. As alleged in further detail at ¶172, according to CW7, Defendants Wiggans and Vontz would consistently direct more product to be shipped to wholesalers than was needed to satisfy the demand.

(h) Confidential Witness 8 ("CW8") is a former Territory Manager who worked at Connetics from 2001 to late 2002 and from November 2005 to August 2006. As alleged in further detail at ¶172, according to CW8, there were discussions among Connetics' employees that Connetics had overstocked with distributors. In addition, CW8 corroborated the information provided by the other confidential witnesses in that Connetics would always hit its Wall Street numbers, even though Connetics' internal sales force would never hit its internal goals for number of prescriptions written.

(i) Confidential Witness 9 ("CW9") is a former Vice President of Sales hired after the Class Period. As alleged in further detail at ¶172, according to CW9, it was obvious that, during the Class Period, the forecast reports would be "changed on a whim," and were often changed on the whims and at the direction of Wiggans and Vontz.

(j) Confidential Witness 10 ("CW10") is a former Regional Sales Director for Connetics from 2003 through November 2005. As alleged in further detail at ¶¶172-173, according to CW10, there seemed to "always be way too much" inventory with Connetics' distributors.

(k) Confidential Witness 11 ("CW11") is a Territory Manager who worked for Connetics for more than six months in 2005. As alleged in further detail at ¶173, according to CW11, it was made clear at sales meetings attended by CW11 in 2005 that prescription levels were not increasing fast enough to offset the buildup of excess inventory with wholesaler distributors. At these sales meetings, it was also made clear that if Connetics had to accept the excess inventory back as a return (if, for instance, it expired before doctors wrote prescriptions for it), then Connetics would take a "big financial hit." CW11 also corroborated the information provided by the other confidential witnesses in that "nobody could understand what was going

on" because prescription totals never matched the amount of product being shipped to distributors even though Connetics' Wall Street numbers always "looked good."

(l) Confidential Witness 12 ("CW12") is a former Senior Associate of Connetics' Regulatory Affairs Division from 2001 to May 2006. As alleged in further detail at ¶51, CW12 primarily acted as Connectics' liason between the FDA and Connetics and was involved in negotiating the trial design with the FDA. As part of CW12's duties, CW12 was apprised of the trials and results. CW12 was deposed by the SEC on this matter.

B. The Allegations Are Further Supported By The SEC's Complaint And Other Filings In The Action *SEC V. Yaroshinsky*

44. Lead Plaintiff's investigation included a review of the publically available court filings and media concerning the case against Defendant Yaroshinsky and Defendant Zak in the federal civil action filed by the SEC. The file includes the original complaint and two amended complaints (collectively, the "SEC Complaint"), answers, a temporary restraining order, a preliminary injunction, sworn declarations of SEC investigators and lawyers, the sworn declaration of Defendant Yaroshinsky, Rule 26(a)(1) initial disclosures, and various motions, which contain facts that corroborate certain of the allegations herein.

45. The SEC is a government agency having primary responsibility for enforcing the federal securities laws and regulating the securities industry and stock market. SEC actions, including the action against Defendants Yaroshinsky and Zak, are brought after an informal investigation reveals enough evidence exists to warrant a formal order of investigation. A formal investigation enables the Enforcement Division's staff to compel witnesses by subpoena to testify and produce books, records, and other relevant documents – as was the case with regard to the complaint filed against Yaroshinsky and Zak. Following an investigation, the SEC staff presents its findings to the SEC's Commission for its review and authorization, which is required before the staff can file a case in federal court or bring an administrative action.

46. In the SEC's case against Yaroshinsky and Zak, according to the sworn declaration of Mark H. Lineberry, the Branch Chief in the Office of Market Surveillance, Division of Enforcement of the SEC, on October 2, 2005, the staff of the SEC Division of Enforcement

received an anonymous complaint from an investor alleging Defendant Yaroshinsky had engaged in insider trading by buying put options in shares of Connetics in advance of the June 13, 2005 announcement concerning the approval of Velac by the FDA.

47. After receiving this anonymous tip, the SEC conducted an extensive investigation, as set forth in the Declaration Of Alan M. Lieberman In Support Of Plaintiff's Motion To Amend The Complaint, dated May 24, 2006 ("Lieberman Decl."). Mr. Lieberman is an Assistant Chief Litigation Counsel with the Division of Enforcement of the SEC. Mr. Lieberman's declaration states at ¶3: "I base this Declaration upon my personal knowledge, which I obtained since March 23, 2006, and upon information provided to me by the staff of the Commission's Division of Enforcement ("staff") assigned to work on this matter. The staff has reviewed trading records, market data, and other relevant documents, conducted telephone interviews, conducted searches of the SEC's database of filings and periodic reports, and discussed this matter with staff of the Food and Drug Administration ("FDA")."

48. The SEC's complaint includes specific dates and times of illegal insider selling and conversations between defendants. The SEC complaint quotes internal Connetics documents, statements made during the FDA's conference call with the Company on April 13, 2005 to discuss the results of the FDA's Executive Carcinogenicity Assessment Committee ("ECAC") review, and the conclusions of the FDA's ECAC concerning the carcinogenicity of the vehicle in Velac.

49. As corroboration, the Company has admitted it assisted the SEC in its investigation, providing documents and responding to questions. As set forth in its Form 10-Q dated August 14, 2006, the Company stated:

> We were notified in April 2006 that we are being investigated by the SEC to determine whether the Company, its employees, officers, directors, or others related to the Company may have violated Federal securities laws. The initial document subpoena requested information relating to our announcement in June 2005 that we had received a non-approvable letter from the FDA regarding Velac Gel, as well as specific information related to certain of our wholesale distributors.

50. Connetics' general counsel confirmed the accuracy of the SEC's allegations set forth in its initial complaint dated March 28, 2006 in an interview with a journalist from the *San Francisco Chronicle.* According to an article published in the *San Francisco Chronicle* entitled

"Insider Lawsuit Is Familiar": "Katrina Church, **general counsel for Connetics,** says **the SEC case doesn't contain any information the company didn't previously know**." In the article, Church states that Connetics investigated Defendant Yaroshinsky's trading activity and took disciplinary action against Yaroshinsky.

51. The SEC also conducted depositions of Connetics employees. For example, CW12, a former Senior Associate of Connetics' Regulatory Affairs Division from 2001 to May 2006 who was involved in negotiating the trial design with the FDA and making sure the Company met FDA standards, stated that the SEC deposed CW12 on this matter.

52. The SEC has demonstrated it likely will succeed on the merits of its claims. On March 28, 2006, the SEC filed an emergency motion for a temporary restraining order to freeze all brokerage accounts in which the proceeds of Defendant Yaroshinsky's fraud had been deposited. On March 28, 2006, the Honorable Michael B. Mukasey entered the temporary restraining order. Defendant Yaroshinsky and the SEC eventually agreed to a stipulated preliminary injunction, entered on March 31, 2006.

53. On November 26, 2007, Defendant Yaroshinsky answered the SEC's complaint, admitting many of the facts contained therein, including the following: Defendant Yaroshinsky admits he was Vice President of Biostatistics and Clinical Operations for Connetics and that he worked on the drug development studies of Velac and the analysis of those results. Yaroshinsky admits to participating in the June 28, 2004 discussions concerning Velac. He also admits to participating in the April 13, 2005 conference call with the FDA, and other Connetics employees, concerning Velac. In a sworn declaration, Yaroshinsky states 14 Connetics employees were on the call. Yaroshinsky admits that on April 13, 2005 – the date of the conference call with the FDA – he called Defendant Victor Zak. Yaroshinsky admits that there were trading bans imposed by the Company after the April 13, 2005 phone call with the FDA concerning Velac. He further admits to selling Connetics common stock and purchasing Connetics puts in the time period and amounts set forth SEC's complaint, including trades on April 21, 2005, April 26, 2005, and April 27, 2005. Defendant Yaroshinsky further admits to opening a brokerage account in the name of his mother-in-law and that he controlled the account and funded the account.

54. Defendant Yaroshinsky's Rule 26(a)(1) Initial Disclosures in the SEC Action identify the following individual who "may testify about the June 28, 2004 meeting of Connetics' toxicology panelists," and according to Lead Counsel's investivation and information and belief, were the members of Connetics' panel of experts: Claudio Conti, DVM, Ph.D., University of Texas, M.D. Anderson Cancer Center; Ronald E. Cannon, Ph.D., National Institute of Environmental Health Sciences; Dana Dunn, formerly of Milestone Biomedical Associates; Peter Mann, DVM, EPL Northeast; R. Michael McClain, Ph.D., McClain Associates; Fred Reno, Ph.D., Toxicology Consultant; David B. Clissold, Hyman, Phelps & McNamara, P.C.; Judson Spalding, Ph.D.; Hilary V. Sheevers, Ph.D., Milestone Biomedical Associates; and Martin L. Wenk, Ph.D., DABT, BioReliance Corporation.

55. On June 19, 2007, the court in the SEC Action entered a Final Judgment as to Defendant Zak, with his consent and without admitting or denying the allegations, for disgorgement in the amount of $863,830.30, plus prejudgment interest thereon in the amount of $81,473.55, but did not impose a civil penalty and waived payment of all but $647,472 of disgorgement and prejudgment interest.

C. The Allegations Are Further Supported By Defendants' Own Statements And Admissions

56. Defendants have themselves admitted to a number of the pertinent facts underlying Lead Plaintiffs' allegations concerning Velac and the accounting fraud alleged herein.

57. With regard to Velac, the Company's amended annual report for 2005, filed with the SEC on July 25, 2006, admits that "on June 10, 2005, the FDA issued a non-approvable letter for Velac Gel, citing that 'a positive carcinogenicity signal was detected in a Tg.AC mouse dermal carcinogenicity study.'" In its June 13, 2005 press release, the Company acknowledged this was the "only issue raised" by the FDA.

58. During a conference call on April 26, 2005, Defendant Wiggans admitted that the Company convened a panel of experts to review the positive dermal in the Mouse Study, the positive dermal was a response to Velac, and management carefully analyzed the results. Further, he admits that the panel was convened prior to the Company submitted its application to the FDA, which was on August 24, 2004. Defendant Wiggans stated:

> [W]e recently received communications that indicated FDA were interpreting results of one our preclinical studies in a different fashion than we did in our submission.
>
> * * *
>
> We conducted one of our preclinical studies in a transgenic mouse model. And in that study, there was a positive response to our product. **At the time, we carefully analyzed the results with a panel of leading experts in this model and leading toxicologists**.

59. Moreover, Defendants' statements during the June 13, 2005 conference call confirm that they knew of no instance in which the vehicle in Velac had even been approved for use outside of the United States. Velac was patent protected, and Defendants would not disclose the composition of the vehicle.

60. In this action, Defendant Zak initially filed an answer [Docket No. 36] in which he admits to selling shares of Connetics stock and purchasing put contracts between April 13, 2005 and June 10, 2005.

61. In the Company's Amended Form 10-K/A for fiscal year 2005 (the "Restatement"), filed with the SEC on July 25, 2006, Connetics and the Insider Defendants admit that during the Class Period the Company issued false and misleading financial statements not prepared in compliance with GAAP. Defendants further admit the financial statements materially understated Connetics' accruals for estimated product rebates, chargebacks, and the amount of future product returns.

V. FACTUAL ALLEGATIONS AND THE FRAUDULENT SCHEME

A. Defendants Conceal Velac's Failure In The Preclinical Tests Required For FDA Approval By 3Q05 Or The PDUFA Date

1. FDA Regulatory Background Information

62. To gain FDA approval to market its dermatological products, Connetics, like other pharmaceutical companies, had to convince the FDA that a particular product was safe and effective. This is accomplished through pre-clinical tests involving laboratory experimentation and animal testing, as well as a series of human clinical trials, which are conducted in three general "phases." In "Phase I," the product is tested on a small number of people (under 100). In "Phase II," between 100 and 300 patients are tested. Finally, "Phase III" trials involve

between 1000 to 3000 patients.

63. Following the Phase III trials, a company seeking approval of its product must submit a "New Drug Application" or "NDA" with the FDA. NDAs contain data from the pre-clinical trials and the Phase I, II and III clinical trials, as well as other information required by the FDA. For instance, 21 C.F.R. § 314.50 provides that an NDA must include a "section describing . . . animal and in vitro studies with the drug, including the following:"

> Studies of the toxicological effects of the drug as they relate to the drug's intended clinical uses, including, as appropriate, studies assessing the drug's acute, subacute, and **chronic toxicity carcinogenicity; and studies of toxicities related to the drug's particular mode of administration or conditions of use**.

21 C.F.R. § 314.50(d)(2).

64. Similarly, the FDA specifies that an NDA must include "a description and analysis of each clinical pharmacology study of the drug, including a comparison of the results of the human studies with the animal pharmacology and toxicology data." 21 C.F.R. § 314.50(d)(5)(i).

65. Without solid clinical data demonstrating the efficacy and safety of the product, the FDA will not approve the product for market and sale in the United States. In particular, if the submitted data suggests that the product is unsafe for ordinary use, the FDA has explicit statutory authority to refuse to approve an NDA. For instance, among other reasons for non-approval, the FDA will refuse to approve an application if:

> The results of the tests show that the drug is unsafe for use under the conditions prescribed, recommended or suggested . . . or the results do not show that the drug product is safe for use under those conditions.

21 C.F.R. § 314.125(b)(3).

66. The FDA approval process has been streamlined by the Prescription Drug User Fee Act ("PDUFA") in an effort to ensure that pharmaceutical companies know the date by which they will receive a determination on their NDAs. According to the FDA:

> In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA). This was reauthorized by the Food and Drug Modernization Act of 1997 and again by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. PDUFA authorized FDA to collect fees from companies that produce certain human drug and biological products. Any time a company wants the FDA to approve a new drug or biologic prior to marketing, it must submit an application along with a fee to support the review process. . . . In the new program, industry provides the funding in exchange for FDA agreement to meet drug-review performance goals, which emphasize timeliness.

67. On October 25, 2004, Defendant Vontz informed investors during a conference call that Connetics had a PDUFA date of June 25, 2005 for Velac. The Company also issued a press release on October 25, 2004 announcing the PDUFA date.

2. Background To The Attempted Development Of Velac At Connetics

68. In May 2002, Connetics acquired from another company the rights for Velac, which the Company described as "a first-in-class combination of 1% clindamycin and .025% tretinoin for the treatment of acne."

69. Velac was a purported breakthrough in the treatment of acne. Previously, no drug successfully combined the "active" ingredients in Velac, clindamycin and tretinoin. Normally, tretinoin and clindamcyin are incompatible agents; tretinoin will cause clindamycin to breakdown. Velac utilized a "vehicle" (sometimes referred to as an aqueous hydrogel) that prevented the breakdown of clindamycin. The vehicle was critically important to the development of Velac. Defendants did not publicly discuss the makeup of the Velac vehicle, claiming its contents are protected intellectual property (as Defendants stated during the Company's June 13, 2005 conference call).

70. There are many acne medications that use similar, if not identical, active ingredients. Some acne medications utilize various combinations of active ingredients that have already been approved by the FDA for individual use. For very good reasons, such combination drugs still must separately obtain FDA approval even though the active ingredients contained therein have been previously approved by the FDA. The FDA requires separate approval for combination drugs containing previously approved active ingredients because, among other reasons, **inactive** ingredients in drugs can be critical to the efficacy of the drug but also unsafe.

71. The vehicle, or base in which the active ingredients are stored and delivered, can have an enormous impact on the efficacy and stability of a product. Vehicles such as aqueous solutions (water-based), creams, gels, lotions, or foams can further define a product as distinct and determines the clinical efficacy and application. The vehicle in addition to providing for product delivery may, in some cases, be necessary for the stability of the product and/or for the preservation of the activity of individual ingredients in combination products. Although in some

cases, vehicles may be simple chemicals or solvents, others are complex and can demonstrate their own biologic activity. For this reason, the FDA may request the inclusion of testing of the vehicle during a new drug application. Presumably the vehicle will not demonstrate any inherent biologic activity and would serve simply as a negative control. For example, in the FDA required label for BenzaClin (as revised on May 23, 2007), the last line of the 4th paragraph mentions that the vehicle was tested in the following text "....statistically significantly higher than that in the sham- and vehicle-controls." Thus, the vehicle in BenzaClin was tested, and the results were as expected and considered negative.

72. Velac, which combined two ingredients found in FDA-approved and popular acne medications in one combination drug, utilized a novel vehicle that was critical to the efficacy of the combination. That vehicle, as Defendants knew, had to be proven safe before Velac could be approved by the FDA.

73. Moreover, even had Velac, or the Velac vehicle, been approved for use outside the United States, it more than likely would have to be independently tested pursuant to United States protocols for FDA approval. The FDA in most cases, if not all cases, requires most new drug applications to independently demonstrate safety and efficacy regardless of use in a foreign jurisdiction. Safety profiles and efficacy data performed without the guidance of the FDA may be not adequate, specifically data obtained in foreign countries may not be considered equivalent to testing in the US. Connetics and the Individual Defendants (other than Zak), as experts in the pharmaceutical industry, would have been familiar with the FDA requirements and would not have made assumptions concerning the acceptance of post-release data from international markets by the FDA when considering safety and efficacy issues.

74. After obtaining the rights to Velac, Connetics and the Insider Defendants informed the market that the Company anticipated filing an NDA "for Velac gel with the FDA during the second half of 2004" and that Velac had "the potential to become [Connetics'] biggest selling product."

75. Throughout 2002, Defendants continued to comment on the importance of Velac. For instance, Defendant Wiggans stated: "Velac was perfect for us. We cannot imagine finding

a better product . . . ."

76. Defendants also reiterated Connetics' anticipated timeline for obtaining regulatory approval of Velac, stating "we expect to meet with the FDA in the second half of the year and begin clinical trials [sic] early part of next year. We remain committed to that time schedule, and we'll keep you updated as this very exciting program moves forward."

77. In December 2002, Connetics initiated the Phase III clinical testing program for Velac. According to Connetics, this phase involved two "pivotal" trials as well as two unspecified studies that the Company described as "two smaller supplemental clinical studies required by the FDA."

78. By late 2003, the Company had completed enrollment in the clinical trials. Many of the clinical trials of Velac took place in Rochester, New York and others took place at the University of Michigan in Ann Arbor, Michigan.

79. As 2003 drew to a close, analysts covering the Company closely followed the Company's statements regarding the clinical trials for Velac, and stated that the drug would provide the Company with significant increases in its revenues and sales. For instance, on January 8, 2004, an analyst from CIBC World Markets issued a report stating that "Connetics announced that it has completed enrollment in its two Phase III clinical trials for Velac Gel . . . our model currently assumes Velac sales of $18.5MM in 2005 and $45.0MM in 2006." (1/8/04 CIBC Report at 1.) Another analyst wrote that "Velac has the largest sales potential, and as a result we believe the outcome of the [Phase III] trial will be one of the major determinants of the direction of [Connetics'] share price." (1/5/04 C.E. Unterberg Report at 1.)

80. On March 23, 2004, Connetics announced the completion of the Phase III testing program for Velac. In a press release issued that day, the Company reported that:

> The data from each trial demonstrated a consistently robust and statistically superior treatment effect for Velac . . . the data from these trials also demonstrated that Velac was safe and well tolerated, with the most commonly observed adverse effects being application site reactions (e.g. burning, dryness, redness and peeling).

81. In commenting on the results of the Phase III trials, Defendant Wiggans stated in that press release that "We are delighted with the strength of the Velac pivotal data . . . as Velac is a patent-protected, first-in-class combination product, we expect it to play an important role as we

build a strong franchise in the $1 billion U.S. acne market . . . and Velac, if approved . . . represents the largest sales potential of any product in our pipeline."

82. Analysts reacted favorably to this news. On March 24, 2004 an analyst from Roth Capital Partners reported that "Connetics announced very strong phase III data in support of Velac Gel . . . the clinical data was robust and showed statistically significant superiority for Velac," and "we believe Velac, a potential first-in-class product, once approved, will rapidly gain share among topical acne alternatives, a $600 million dollar drug class." (3/24/04 Roth Capital Report at 1.) Another analyst wrote on March 24, 2004 that "the data from these trials also demonstrated that Velac was **safe and well tolerated"** and "for '05, we estimate Velac sales of $18.5MM, ramping up to $45MM in '06." (CIBC Report at 2 (emphasis in original).)

83. The Company continued to promote Velac through the first and second quarters of 2004. On a conference call with investors held on May 4, 2004, Defendant Krochmal stated "I believe that the exceptional result that we've seen for Velac for both efficacy and safety may lead me to conclude that Velac will become the topical treatment of choice for inflammatory and noninflammatory acne."

3. Defendants Concealed Critical Information Concerning The Velac Vehicle

84. Prior to and throughout the Class Period, Defendants emphasized that Velac is a "combination" drug made from two popular acne medications – both of which have been previously approved by the FDA. For example, on March 23, 2004, Defendants caused Connetics to issue a press release announcing the results of Connetics' Phase III trials of Velac, in which the Company described Velac as follows:

> Velac is a once daily topical treatment that combines clindamycin, the No. 1 prescribed topical antibiotic for acne, and tretinoin, the No. 1 prescribed topical retinoid for acne. The combination drug has a triple-action effect combining the anti-inflammatory and antimicrobial effects of clindamycin with the beneficial comedolytic effects of tretinoin in normalizing the plugging of pores, which leads to acne lesions. Velac is delivered in an elegant, non-alcoholic gel. . . . Velac is approved in Europe.

85. Despite the critical importance of the vehicle in Velac, as set forth in ¶¶69-73, Defendants did not disclose material facts known to them concerning the vehicle, including: (i) Defendants learned no later than June 2004 that Velac tested positive as a tumor promoter or

carcinogen in a pre-clinical study performed by the Company; and (ii) Defendants knew, but failed to disclose, that the positive carcinogenicily test made it virtually impossible for the Company to obtain FDA approval by 3Q05 or the PDUFA date due to the required further testing.

86. By referring to Velac as a combination of two popular, FDA-approved drugs, Defendants led the market to conclude that FDA approval would not be difficult and could be expected by 3Q05. For instance, on September 29, 2004, an analyst from Jefferies & Company, Inc. reported his conclusion that Velac faced "minimal obstacles" to approval:

> Velac could emerge as a leading therapy option for acne. **Velac combines two popular acne treatments**, clindamycin and tretinoin. The NDA was filed this month ([exact] date was not disclosed for competitive reasons), and we expect a response in 3Q05. **We believe Velac gets approved with minimal obstacles** and becomes a significant growth driver for Connetics on its path to becoming a leading acne therapy.

87. During the Class Period, as set forth in Section VI detailing Defendants' false and misleading statements, Defendants continued to give investors every indication that Velac would be approved by 3Q05 or the PDUFA date. Indeed, during the Class Period – until June 13, 2005 – Defendants' public revenue guidance for 2005 included approximately $20 million of Velac sales for the approximately six month period in 2005 occurring after Velac obtained FDA approval.

a. No Later Than June 2004, Defendants Learned The Velac Vehicle Caused Cancer In Laboratory Mice

88. CW1 was a former Director of Pharmacology and Toxicology from August 1999 to June 1, 2004, who reported to Defendant Vontz. CW1 ran some of the pre-clinical studies for Velac. Before Connetics chose a model for conducting its pre-clinical testing, CW1 met with Connetics' PDRC, which included among others, Defendants Higgins, Wiggans and Vontz. At this meeting, CW1 explained that Connetics could conduct a transgenic mice study, in which the mice have a gene mutation that makes them more sensitive for tumor growth, or they could use a traditional method with normal mice. The transgenic mice study would only take ten months to complete whereas the traditional method would require three years. According to CW1, the Committee decided to use the transgenic mice model because time was critical and, in the

pharmaceutical industry, there is always pressure to get the drug out before another company does. According to CW1, the Mouse Study began in the second half of 2003 or early 2004 and was conducted at an outside toxicology lab in Washington. CW2, of BioReliance Corporation, who attended the meeting of Connetics' June 28, 2004 expert panel, confirmed that BioReliance conducted the testing for Connetics.

89. From January 2004 through June 2004, the Company performed the Mouse Study to assess Velac's safety by determining whether it caused cancer in laborartory mice. No later than June 2004, senior executives of Connetics were aware that Velac had tested positive for being a carcinogen.

90. According to CW3, Defendants Yaroshinsky, Vontz and Krochmal were directly in charge of overseeing the pre-clinical testing of Velac and were involved in every step of the developmental process for the drug, including oversight of the Mouse Study. Throughout the Class Period, Yaroshinsky reported directly to Vontz and Krochmal and provided regular updates on the Velac regulatory process to certain members of the Management Executive Committee, including Wiggans and Higgins.

91. CW4 served as the commercial representative for Velac and was kept informed as to its progress towards approval for commercial sale. According to CW4, there were clear signs before April 2005 that the Company would have problems getting Velac approved by the FDA. For instance, in late 2003 or 2004, CW4 attended an Executive Committee Meeting that was also attended by Jay Finister (Senior VP of Marketing), Danine Summers (VP of Marketing), Dr. Xinfan Huang (Director of Pharmacology and Toxicology and lead pre-clinical scientist for the Mouse Study, who left Connetics June 1, 2004), Defendant Vontz, Defendant Higgins, Defendant Wiggans and others. According to CW4, Dr. Huang gave a presentation at the meeting concerning the Mouse Study and it was clear that there were high incidences of tumors in the mice in the study. During this meeting, the attendees discussed how to "risk mitigate" the findings of the Mouse Study.

92. According to the SEC, as corroborated by Lead Counsel's investigation as set forth in Section IV, by no later than mid-June 2004, Connetics received the results of the Mouse

Study and learned that **89 out of 160 of the mice (approximately 56%)** treated with Velac developed cancerous skin tumors. According to CW4, Wiggans and Higgins "absolutely" would have been kept apprised of the Mouse Study results for Velac.

93. Specifically, the Mouse Study results obtained by Connetics and the Individual Defendants (other than Zak) in mid-June 2004 revealed the vehicle was potentially a tumor promoter or carcinogen. Based on the Company's own Mouse Study, the FDA's Executive Carcinogenicity Assessment Committee ("ECAC") would later conclude that the "**vehicle** was positive in this assay and may be a tumor promoter or a carcinogen."

94. On June 28, 2004, Connetics convened a panel of toxicology experts to provide feedback on the results of the Mouse Study. The members of the panel were required to sign confidentiality agreements covering the discussions of the meeting, and the Company collected the data provided to the experts after the meeting was concluded. At the June 28, 2004 meeting, the Company's panel of expert toxicologists informed Connetics that the panel **did not know of any drug that exhibited a "positive dermal" similar to Velac that ever had been approved by the FDA**.

b. No Later Than June 2004, Defendants Knew Velac Would Not Be Approved By Either 3Q05 Or The PDUFA Date – Which Was Critical To The Company

95. Throughout the Class Period, Defendants issued public revenue and earnings guidance that included sales of Velac beginning in the 3Q05. Defendants' revenue and earnings forecasts required Velac approval by no later than the 3Q05, and after the Company submitted its NDA on August 23, 2004, the revenue and earnings forecasts anticipated Velac's approval by no later than the PDUFA date of June 25, 2005.

96. In truth, however, Defendants knew no later than June 2004 that Velac would not be approved by the FDA within the time frame required by the Company's revenue guidance. According to CW5, a recognized expert in use of the Tg.AC mouse study who served as an expert on the toxicology panel convened by Connetics to analyze the results of the Mouse Study, if a drug is tested on Tg.AC mice and the mice develop tumors, it at least means that further testing needs to be done. Moreover, according to CW5, if you are testing 100-200 animals and

20% develop tumors, it would be considered significant. Here, as set forth in ¶92, the Mouse Study resulted in far more than 20% of mice developing tumors. Indeed, according to the SEC after conducting its extensive investigation including obtaining and reviewing documents, 56% of mice developed tumors.

97. According to the CW5, the FDA would not approve a drug that had positive results in the Tg.AC study without further testing. Conducting carcinogenicity testing necessarily takes at least another six months to complete (if the Company conducted a Tg.AC mouse study) or could take as much as two years or more (if, for example, the Company conducted a rat study or a study on mice not genetically altered).

98. CW6 was a former Connetics Senior Manager of Regulatory Affairs from October 2001 to February 2007, whose job it was to handle dealings with the FDA. According to CW6, once the Company learned the results of the Tg.AC Mouse Study, there was nothing the Company could do to prove Velac was safe other than a two year CARC study.

99. Because the Company, at the very least, had to perform additional carcinogenicity testing in order to obtain FDA approval, Defendants knew that it was not possible for the Company to obtain FDA approval of Velac by 3Q05.

100. It was important to Defendants (except Zak) that Connetics obtain approval of Velac within the time frame they had told investors. First, Connetics' revenue forecasts for 2005 included Velac sales of $20 million in 2005. Without approval of Velac, or the appearance that approval was likely prior to the PDUFA date, Defendants would have to lower revenue guidance, which would impact the Company's stock price. Second, Defendants knew that a competitor, Medicis, was developing a competing drug named Ziana, which the Company admitted in a press release. Defendants, who are professionals in the pharmaceutical industry, knew Connetics would have a competitive and marketing advantage over Medicis if Connetics could obtain approval of its drug (Velac) before Medicis could obtain approval of its drug (Ziana). According to CW6, in the pharmaceutical business time is money.

4. Defendants Misled The Market About Velac For Nearly A Year After They Learned That Velac Caused Cancer In Laboratory Mice

101. By June 2004, Connetics and the Insider Defendants knew or should have known that Velac caused cancerous tumors in laboratory mice and that the FDA was unlikely to approve Velac by either 3Q05 or the PDUFA date. However, rather than immediately disclose this critical information to investors – and risk the sudden and certain decline in the price of Connetics' securities that would ensue – the Insider Defendants and Connetics hid the significant problems with Velac and actively mislead investors regarding Velac's prospects for approval by the FDA.

102. For instance, after the Company's July 28, 2004 press release and Defendants' conference call with investors, analysts covering Connetics reacted favorably to the Defendants' misleading statements concerning Velac and published reports including in their assumptions of Velac revenue in 2005. An analyst report issued on July 29, 2004 estimated that the Company would realize $18.5 million in revenue from sales of Velac in 2005. (7/29/04 CIBC Report at 5.) As a result of Defendants' misleading statements, on July 29, 2004, Connetics common stock closed at $27.28 per share, an 18% increase on heavy trading volume, over its closing price of $23.22 on July 28, 2004.

103. As discussed in Section VI below, throughout the remainder of 2004 and into the second quarter of 2005, Connetics continued to make positive statements regarding Velac. Analysts covering the Company reacted favorably to the Defendants' positive statements, and focused on Velac's anticipated positive impact on Connetics' future sales and profits.

104. For instance, on March 16, 2005, Connetics filed its Form 10-K for the fiscal year ended 2004, which stated that "Velac was safe and well tolerated, with the most commonly observed adverse effects being application site reactions such as burning, dryness, redness and peeling." (3/16/05 Form 10-K at 51.) Responding to these disclosures by Defendants, an analyst wrote on March 16, 2005 that "we have moved Velac's [anticipated] launch into 3Q05 as **the company continues to express confidence in the product's timing** . . . this raised our '05 and '06 sales forecast from $8 mil to $40 mil and $15 mil to $45 mil, respectively." (3/16/05 C.E.

Unterberg Report at 1.)

105. Because the Insider Defendants and Connetics concealed from the market the results of the Mouse Study and the conclusions of their own toxicology experts, the market remained unaware of the material problems with the safety and approvability of Velac. Indeed, based on Defendants' public statements about Velac (set forth in Section VI below), the market reasonably anticipated that Velac would be approved by the FDA in mid-2005 and begin generating millions of dollars in revenue for the Company by the second half of 2005.

106. On April 13, 2005, Connetics common stock closed at nearly $28 per share, and its convertible notes traded as high as $12.60 per note.

5. The April 2005 Teleconference With The FDA

107. On April 13, 2005, Connetics held a private conference call with members of the FDA's Executive Carcinogenicity Assessment Committee ("ECAC") for the purpose of discussing the FDA's comments and conclusions on the NDA for Velac. The FDA's ECAC is the primary resource for the FDA on carcinogenicity issues. It is responsible for, among other things, evaluating carcinogenicity study results, data generated from dose selection studies, and proposed carcinogenicity protocols. Defendant Yaroshinsky, in his capacity as Connetics' Vice President of Biostatistics and Clinical Operations, participated on that call along with other senior members of Connetics management including, on information and belief, Defendant Krochmal. CW6 also participated in the call.

108. During that call, members of the ECAC repeated the information that Connetics' own toxicology experts had told Connetics on June 28, 2004 – namely, that the "positive dermal" experienced in the Mouse Study was a serious impediment for the approval of Velac for market and sale in the United States. According to CW6, it did not look good for obtaining approval of Velac. According to the SEC, the ECAC told Connetics (including Defendant Yaroshinsky and, on information and belief, Defendant Krochmal) that:

(i) "[Velac] may be a tumor promoter or a carcinogen"; and

(ii) "**this is a serious issue for a topical product for the treatment of acne**."

109. These comments by the FDA's ECAC confirmed the serious issues regarding the

safety and approvability of Velac within Connetics' timeframe that the Insider Defendants, Yaroshinsky and Connetics had known since at least June 28, 2004.

110. The comments and conclusions of the FDA's ECAC were immediately relayed to Connetics' senior management, including Defendants Wiggans, Higgins and Vontz. Recognizing that a formal FDA non-approvable letter was now imminent (and the eventual receipt of such a letter could not be hidden from the market the way that the Insider Defendants and Connetics had concealed the Mouse Study), on April 14, 2005 Connetics' senior management imposed a ban on trading in Connetics' securities, which prohibited any employees who had attended the conference call with the FDA or were involved in preparing regulatory submissions for Velac from trading in the Company's securities. This trading ban could not have been put into place without the approval of Wiggans, Higgins and Vontz, thus confirming that these Defendants were promptly informed of the FDA's comments on the April 13, 2005 conference call (the substance of which they already had known for nearly a year).

6. The Day After The FDA Conference Call, Defendants Make False and Misleading Statements About Velac Driving Up The Company's Share Price

111. On April 14, 2005, the day after Defendants' conference call with the FDA concerning Velac and the same day the Company instituted a trading ban in Connetics stock, Connetics hosted their annual 2005 Analyst and Investor Day in New York City.

112. During the Company's Analyst and Investor Day, which was available via webcast and was attended by numerous analysts, Defendants (specifically Wiggans and Connetics, and on information and belief, the conference was attended by Higgins and Krochmal) increased the Company's 2005 revenue guidance (which included revenues from sales of Velac). In addition, Defendants made favorable presentations concerning Velac without disclosing the fact that they had been told by the FDA it had serious concerns about the safety of Velac.

113. As detailed in Section VI, after attending the Analyst and Investor Day, numerous analysts reported on Defendants' false and misleading statements. For example, one analyst reported in a report issued April 15, 2005, the "Company appeared enthusiastic in the R&D

overview about the Velac studies" and noted Connetics "appears to be confident in approval" – leading that analyst to conclude "we expect this combination acne drug to receive an outright approval on June 25th."

114. Another analyst reporting on Defendants' statements at the Analyst and Investor Day, issued a report on April 14, 2005 titled "Analyst Day Highlights; All Eyes on Velac." The report stated, among other things, "Connetics provided additional clinical info on Velac" and "the Company is positioned on the verge of launching its first potential $100MM therapeutic, Velac, with FDA approval anticipated mid-year."

115. From April 13, 2005 to April 26, 2005, as the Insider Defendants and Connetics concealed the comments of the FDA's ECAC (and the other issues with Velac) and misrepresented the likelihood of Velac being approved, Connetics' stock price increased nearly 9 percent, and the prices of its convertible notes increased nearly 6 percent.

7. Defendants Partially Reveal The Truth Concerning Velac

116. After the market closed on April 26, 2005, Connetics finally issued a press release that partially disclosed certain aspects of the issues raised by the FDA. The press release stated that the FDA was "interpreting some of the results of a pre-clinical study for Velac Gel differently than the Company did in the NDA submission . . . ."

117. The April 26, 2005 press release also stated:

> **The Company carefully analyzed the results with a panel of leading toxicologists and experts in this model.** The experts advised the Company that the transgenic mouse model is known to have limitations, and the experts concluded that the positive response was the result of a limitation of the model. The advice of these experts is supported by other products which had a positive finding but were ultimately approved based on additional work in other animal models."

118. In addition, as set forth in greater detail in Section VI, Defendants held a conference call for investors on April 26 in which Defendants made a number of false and misleading statements to alleviate investor concern that Velac would not be approved by the FDA by the PDUFA date. For instance, Defendants confirmed the Company's previous 2005 EPS guidance of $0.88-$0.92, which included $20 million in revenue from Velac. This information was noted by analysts, with one analyst stating in a report issued on April 27, 2005

that "Connetics hopes to satisfy FDA concerns [regarding Velac] before the June 25th PDUFA date and reiterated 2005 EPS guidance of $0.88-$0.92."

119. Although Defendants disclosed certain limited aspects of the issues with Velac, the April 26, 2005 Press Release and the Defendants' conference call were materially false and misleading because, among other things, Defendants (i) failed to disclose the specific information that the ECAC told Connetics that "this is a serious issue for a topical product for the treatment of acne," (ii) failed to inform investors that Connetics had been aware of the "positive dermal" in the Mouse Study for nearly a year; and (iii) it was directly contrary to the information that Connetics had received from its own panel of toxicology experts on or about June 28, 2004, that they were aware of no drug exhibiting a "positive dermal" such as Velac that had **ever** been approved by the FDA.

120. In the April 26 conference call, Wiggans said "[w]e conducted one of our pre-clinical studies in a transgenic mouse model. And in that study, there was a positive response to our product. At the time, we carefully analyzed the results with a panel of lead experts in this model and leading toxicologists." Wiggans further stated that the panel "concluded that the positive response was a result of … limitations of the model." He also stated that other products, specifically benzoyl peroxide, "have had a positive finding in this model, resulting in a clinical hold, only to be released later, based upon submission of additional data." Wiggans stated that the Company is "very committed to working with the FDA to get them the information so this issue can be resolved and enable us to launch Velac on schedule."

121. Defendants' statements comparing the attempted development of Velac to the FDA's approval of benzoyl peroxide were misleading for several reasons. As set forth herein at ¶¶96-99, the FDA would not approve a drug that tested positive in a Tg.AC test without further additional testing. As Defendants knew, additional testing would take months, if not years, and therefore could not be done prior to the PDUFA date. *See* ¶98 (CW6); ¶88 (CW1). Moreover, Defendants failed to explain how the test results between Velac, including its vehicle, were similar to (undisclosed) test results for benzoyl peroxide.

122. In addition, Defendants could not have believed that, because benzoyl peroxide

medication (or any other acne drug) obtained FDA approval after a positive carcinogenicity test result, they too would obtain FDA approval of Velac by the PDUFA date. Benzoyl peroxide, containing single active ingredient medication, and related combination drugs such as BenzaClin are different than Velac (or Velac's active ingredients and vehicle). All new drugs, including combinations of existing drugs, require independent safety testing by the FDA before approval. It would be baseless to draw parallels or make comparisons concerning safety issues between drugs containing different active and inactive ingredients. Moreover, the product insert provided with BenzaClin (prior to May 23, 2007) disclosing that it was approved by the FDA despite benzoyl peroxide having tested positive in a Tg.AC mouse study does not disclose obvious critical facts necessary for drawing any legitimate comparison to Velac, including: (i) the actual test results and/or instances of tumors incurred by mice in the study; or (ii) whether benzoyl peroxide was required to undergo further testing to demonstrate its safety after the Tg.AC mouse study was conducted. According to a medical expert, and confidential witnesses in a position to know about such matters, once a drug tests positively in a Tg.AC mouse study it is very unlikely the FDA will approve it unless further testing is done to demonstrate its safety. Disclosure that further testing was performed, however, may not be included in a product insert such as that for BenzaClin.

123. There are significant reasons to not compare Velac, a novel combination product containing clindamycin and tretinoin, with BenzaClin, which had already been approved, including: (i) combination products should not be considered comparable based on similarities of their ingredients, particularly if the active ingredients are not even the same compounds, as in a comparison of Velac to BenzaClin; (ii) combination products still require independent approval by the FDA even if they contain active ingredients already approved by the FDA; (iii) the impact and safety profile of a novel vehicle should not be discounted and a positive finding for a vehicle control could warrant additional testing and may cause one to question the biologic insignificance of the vehicle; and (iv) the content of a product insert represents a synopsis and does not include reference to all of the supporting data or additional steps undertaken during the FDA approval process.

124. Statements found in one product insert cannot be taken out of context to apply to

another product deemed similar without the instruction of the FDA since when taken out of the context of the product insert these statements fail to reflect all of the safety testing that was done during the approval process of the approved drug. This would include those tests not listed or which are later required by the FDA. Unless specifically provided with an opinion directly from the FDA, it would be difficult to state that findings found in one product insert could be found applicable to any other product that was not identical to the first product.

125. In addition, Defendants failed to disclose on April 26 that the FDA's ECAC had concluded that the "**vehicle** was positive in this assay and may be a tumor promoter or a carcinogen." This was particularly significant because, even after the Company issued its April 26, 2005 press release, investors continued to believe approval of Velac was more likely because the two active ingredients in Velac had already been approved by the FDA and were popularly prescribed medications. Indeed, immediately after the Company's conference call on April 26, 2005, one analyst wrote: "The factors that are in favor of Velac's approvability include . . . [t]he active ingredients (clindamycin and tretinoin) are FDA-approved."

126. Even though the April 26, 2005 press release and conference call failed to disclose the full extent of the serious issues facing Velac, Connetics' stock dropped upon those partial disclosures. On April 27, 2005, Connetics common stock closed at $22.30, down $5.27 from its $28.24 closing price on April 26, 2005, a 17% decrease, on heavy trading volume. Connetics' convertible notes dropped from a previous high of $133.90 to $111.66, a 20% decrease.

8. <u>The FDA Sends A Non-Approval Letter On Velac</u>

127. Following Connetics' April 26, 2005 announcement, the market remained optimistic that Velac would be approved by the FDA based on existing test data. For instance, before the market opened on June 10, 2005, an analyst from CIBC World Markets issued a report that stated, among other things:

- "according to [Connetics] management, its experts advised the [positive dermal] was apparently a false positive . . ." (6/10/05 CIBC Report at 2);
- "**management believes it can address FDA commentary with existing data**," (*Id*. (emphasis in original));

- "**Velac could generate at least as much as the heavily genericized clindamycin market alone, indicating peak sales of over $100 MM**." (*Id*. at 3 (emphasis in original)).

128. After the close of the market on Friday, June 10, 2005, Connetics received from the FDA a formal "non-approvable" letter for Velac. According to the SEC, the FDA's letter stated that the drug was "unsafe for use."

129. On Monday, June 13, 2005, before the market opened, Connetics issued a press release and Form 8-K disclosing that the FDA had not approved Velac. The press release stated that "the only issue raised in the non-approvable letter was a positive carcinogenicity signal that was detected in a TgAC mouse dermal carcinogenicity study." In other words, the FDA had refused to approve Velac based solely on the results of the Mouse Study – results that the Defendants had known of (but did not disclose to the market) for **nearly a year**.

130. In that press release, Connetics reduced its guidance to account for the non-approval of Velac, stating that: "as a result of today's announcement, Connetics now projects 2005 total revenues to be $182 million to $188 million, down from previous guidance of $195 million to $206 million. Combined SG&A and R&D expenses for 2005 are projected to be between $121.5 million and $125.0 million. Diluted EPS for 2005 is projected to be in the range of $0.66 to $0.70, versus previous guidance of $0.88 to $0.92."

131. After issuing the press release, at 8:00 A.M. Eastern, the Company held a conference call for analysts and investors in which Defendants attempted to conceal their misconduct. On the conference call, the Company's Director of Investor Relations, Patrick O'Brien, and Defendant Wiggans specifically stated Defendants never had any indication there was a problem with the preclinical animal testing of Velac:

> DEB KNOBLEMAN: Just two follow-ups. Number one, do you get the sense that the FDA had any concerns around the preclinical data -- well, assuming that you did do preclinical trials specifically on Velac in combination which is the clindamycin and the tretinoin? Were there any questions or concerns around that arm of the preclinical data?
>
> PATRICK O'BRIEN: I think, as we've said and without getting into specific details, **we have a lot of indications that the package and the data set was very complete up until a month and a half ago**. And even after that, as I alluded to, the NDA review process seemed to be continuing to proceed. So I can tell you

> that we didn't really have -- **we didn't really have any type of a heads up on this**.
>
> * * *
>
> TOM WIGGANS: Let me just leave it as **there was a pretty comprehensive preclinical package that we submitted and we were proud of.** And so I think because **they only raised this specific question -- or this specific issue when we got the letter on Friday** I think that's what we're going to zero in on.

132. The price of Connetics' stock collapsed on this news, dropping approximately 27% from its closing price of $20.77 on June 10, 2005 to $15.13, on heavy trading volume. Connetics' convertible notes dropped from $110.61 to $96.08, a 16% decrease.

9. Yaroshinsky And Zak Made Hundreds Of Thousands Of Dollars Short-Selling Connetics' Securities Based On Their Inside Knowledge About The Problems With Velac

133. As set forth in the SEC Complaint, on April 13, 2005, shortly after the conference call with the FDA discussed above, Defendant Yaroshinsky telephoned his friend and former neighbor, Defendant Zak, at Zak's office in Connecticut. On that call, Yaroshinsky told Zak about the comments and conclusions of the FDA's ECAC.

134. Following this call, and as set forth in the SEC Complaint, Defendant Zak immediately accessed his online brokerage account using his office computer, and sold short 7,000 shares of Connetics, and liquidated 3,000 shares from his previously held long position in Connetics common stock. Between April 14, 2005 and June 10, 2005, Zak sold short an additional 68,000 shares of Connetics common stock and purchased 430 "put contracts" in Connetics' common stock. Put contracts are a type of option where the value of the put contract increases as the price of the underlying security – in this case, Connetics' common stock – declines.

135. On April 14, 2005, Connetics instituted a trading ban for certain of its employees, including Yaroshinsky, and Defendant Yaroshinsky opened a nominee brokerage account in the name of his mother-in-law that he funded and controlled.

136. On April 21, 2005, Defendant Yaroshinsky purchased 5 put contracts in the nominee account under the name of his mother-in-law.

137. On April 27, 2005, following Connetics' partial disclosure of the FDA's concerns about Velac, Defendant Yaroshinsky sold 15,100 shares of his 16,913 share long position in Connetics common stock, which Yaroshinsky had accumulated over the course of several years. On the same day, Defendant Yaroshinsky purchased 41 put contracts on Connetics stock.

138. On May 12, 2005, Defendant Yaroshinsky funded the nominee account (held in his mother-in-law's name) with $363,000 from his own brokerage account. On June 6, 2005, Yaroshinsky deposited $150,000 from his checking account into the nominee account.

139. Between May 12, 2005 and June 10, 2005, Defendant Yaroshinsky purchased 2,020 put contracts in the nominee account.

140. Following the collapse of Connetics' stock price after the disclosure of the FDA's non-approvable letter on June 13, 2005, Defendant Yaroshinsky closed out more than 2,000 of his put contracts.

141. Defendant Yaroshinsky profited by more than $680,000 on his transactions in Connetics' securities while in possession of material non-public information.

142. Defendant Zak profited by more than $900,000 on his transactions in Connetics' securities while in possession of material non-public information.

10. The SEC Investigation Into Velac

143. For nearly a year after Connetics announced its receipt of the FDA non-approvable letter for Velac, the Insider Defendants and Connetics managed to conceal from the market the fact that they had known of the serious issues relating to Velac long before they were disclosed to investors. This information was not revealed until nearly a year later in a series of disclosures following the SEC's investigation into Defendants Yaroshinsky and Zak's insider trading.

144. On March 28, 2006, the SEC announced that it had filed suit in the United States District Court for the Southern District of New York against Defendant Yaroshinsky, charging him with illegally trading on non-public inside information about Velac. The SEC press release stated:

> The Commission's complaint alleges that Yaroshinsky, who participated in tests which led the FDA to ultimately conclude that the drug [Velac] was "unsafe for use," learned the FDA's preliminary views with respect to the cancer tests in an April 13, 2005 call with the FDA. Shortly thereafter, Yaroshinsky positioned

> himself to profit from a fall in the price of Connetics' stock . . . . Ultimately, on June 13, 2005, when news of the non-approval was made public, Connetics' share price fell 27% and Yaroshinsky reaped a benefit of at least $680,000.

145. In an interview with the *San Francisco Chronicle*, Connetics' general counsel stated that the complaint does not allege any information that the Company did not already know.

146. On June 22, 2006 the SEC filed an amended complaint against Defendant Yaroshinsky, which included more details regarding the Mouse Study and also named Defendant Zak as a Co-defendant. The SEC issued a press release on June 23, 2006, which stated:

> The Amended Complaint alleges that Zak, a resident of Newton, Massachusetts, received material non-public information from Yaroshinsky concerning the FDA staff's preliminary analysis of the carcinogenicity tests of Velac Gel, an acne drug being developed by Yaroshinsky's then employer . . . the Amended Complaint alleges that both Zak and Yaroshinsky traded on the basis of this information. In the end, Zak profited from his illegal trading by more than $900,000 and together, Yaroshinsky and Zak benefited financially by more than $1.58 million.

147. Following this partial disclosure, the price of Connetics' common stock dropped from a closing price of $12.44 on June 22, 2006, to close at $11.96 on June 23, 2006, and continued to fall to a closing price of $10.74 on June 27, 2006.

B. Connetics Issued Materially False And Misleading Financial Statements During The Class Period

148. At the same time that the Insider Defendants were making material misstatements to the market regarding the safety and approvability of Velac, they were also causing Connetics to issue and publicly-file with the SEC materially false financial statements. Throughout the Class Period, Connetics regularly reported numbers that matched or exceeded Wall Street's published estimates for the Company's quarterly and yearly financial performance (only missing earnings in 4Q05). As discussed below, however, Connetics was "making its numbers" only because the Company was engaged in an array of improper and fraudulent accounting manipulations that artificially inflated the Company's revenues and earnings in violation of the most basic principles of GAAP.

1. The Marketplace For Connetics' Products And The Company's Method For Recognizing Revenue

149. During the Class Period, Connetics, like most pharmaceutical companies, did not sell its products directly to doctors or patients. Rather, Connetics sold its products to a handful of large "distributors," and these distributors placed the products in inventory for subsequent sale into the retail marketplace. For instance, for the fiscal year ended December 31, 2005, Connetics sold the vast majority of its products to just three distributors – Cardinal Health, Inc. ("Cardinal"), located in Dublin, Ohio, McKesson Corporation ("McKesson"), located in San Francisco, California, and AmerisourceBergen Corporation ("AmerisourceBergen"), located in Chesterbrook, Pennsylvania. These distributors accounted for 36%, 34% and 11%, respectively, of Connetics' total reported product revenues for that year. Connetics also sold its products to an undisclosed "nationally based international distributor," which, on information and belief, is Pharmed Group Corp., located in Miami, Florida.

150. The marketplace for Connetics' products during the Class Period worked as follows. Connetics would market its prescription medications primarily to doctors and other medical professionals. When a doctor wrote a prescription for a patient to use a Connetics product, patients, for the most part, would fill their prescriptions at retail pharmacies. The majority of retail pharmacies would, in turn, purchase their prescription medication from the large industry-wide distributors such as Cardinal Health, McKesson, and AmerisourceBergen that served as Connetics' primary customers. The distributors then sold their inventory of Connetics' products to the pharmacies or other retail users to fulfill prescription demand.

151. Throughout the Class Period, when Connetics sold products to its distributors, those sales were subject to certain payment conditions pursuant to which the distributors could return the products or receive significant refunds or discounts off of the sale price. The three largest conditions of sale were rebates, chargebacks and right of return. These are discussed below.

152. Rebates. Throughout the Class Period, Connetics offered rebates, or refunds, to various government programs and private health organizations that purchased Connetics products. Certain of these rebates were made available to managed care providers in exchange for these

customers purchasing large volumes of Connetics products. Other rebates were extended under the Federal Medicaid Rebate program, pursuant to which Connetics was required to pay a rebate to state and federal governments for products purchased by state and local Medicaid programs. In addition, Connetics was required to extend certain pricing discounts to various governmental agencies so that those agencies would receive the "best price" that Connetics offered on its products to any other wholesaler, distributor or other customer.

153. Chargebacks. Pursuant to the Veterans Health Care Act of 1992, certain federal entities such as the Veterans Administration, the Department of Defense and the Coast Guard were entitled to a discount of approximately 24% off of the average manufacturer price that Connetics charged to non-federal customers. When one of these federal entities purchased Connetics' product from a wholesale distributor, the distributor would "charge back" to Connetics the difference between the then-current retail price of the product and the price that the federal entity paid to the distributor for the product.

154. Returns. Throughout the Class Period, Connetics allowed distributors and pharmacies to return unused products that were within six months of expiration and to return expired products within one year **after** their expiration date. Connetics also allowed customers to return damaged products. When a distributor or pharmacy returned a product, Connetics would provide the customer with a credit in the amount of ninety-five percent of the then-current wholesale price of the product.

155. Despite refund, chargeback and return conditions that applied to each product Connetics sold to its distributors, throughout the Class Period, Connetics would "book" the revenue from the sales of its products at the same time the products were shipped to the distributors. When Connetics booked the revenue from these "sales," it would set aside a fixed amount of accruals and allowances – *i.e.*, reserves – to account for the possibility that its "sales" revenue would be subsequently reduced by rebates, refunds, chargebacks or returns received from customers. Connetics would determine the amount of accruals and allowances by evaluating factors including the Company's historical experience selling the product and the competitive marketplace.

156. As discussed below, in order to comply with GAAP, Connetics was required to have a good faith basis for its estimated reserve accruals. Indeed, it was critical that Connetics honestly and accurately estimate the future rebates, chargebacks and returns of its products and record appropriate accruals for those amounts. If, for instance, Connetics deliberately underestimated these amounts, then its "sales" and "product revenue" would be artificially inflated, and when future returns and rebates came due, the Company would not have sufficient reserves to pay for them.

2. Defendants Closely Monitored And Maintained Distributors' Inventory Levels

157. Connetics' SEC filings recognized under the heading "Critical Accounting Policies and Estimates" that it was imperative for the Company to closely monitor the level of inventories in the distributor channel as this directly impacted the Company's reported earnings. For instance, under the heading "Critical Accounting Policies and Estimates," the Company's 2004 Form 10-K filed with the SEC on 3/16/2005 stated: "We recognize product revenue net of allowances for estimated discounts, returns, rebates and chargebacks. . . . **We monitor inventories in the distributor channel to help us assess the rate of return**." The Company made a nearly identical disclosure in its 2003 and 2005 Form 10-K. The Company's SEC filings further state that Connetics' "senior management has reviewed these critical accounting policies and related disclosures. . . ."

158. Defendants assured investors the Company monitored inventory levels in numerous ways to assure Connetics accurately understood the amount of product held by distributors – which the Defendants admitted was critical to its accounting. The Company's Form 10-K for 2003 filed with the SEC on March 15, 2004 stated:

> We monitor wholesaler inventory **using a combination of techniques**, including evaluating how much inventory is sold through to the wholesalers' customers, which we do **by tracking the prescriptions filled for our products at the pharmacy level**. . . . We estimate prescription demand for our products primarily by analyzing third-party syndicated data sources that **track prescriptions written by health care providers and dispensed by licensed pharmacies**.

159. According to the Company, it purchased data on prescriptions filled from Per-Se Technologies, formerly NDC Health Corporation, one of the leading providers of prescription-

based information. This information would enable Defendants to monitor any inventory data received from the Company's distributors.

160. Accordingly, because the Company was able to obtain data on the number of prescriptions written and filled for its drugs – and the Company knew the amount of each drug it shipped to distributors or elsewhere – the Company was able to estimate the amount of inventory outstanding at any one time without relying upon data from its distributors.

161. Defendants told investors that in 2004 Connetics took further steps to ensure it closely monitored and controlled inventory levels at distributors. For instance, during a Conference Call with investors and analysts on August 2, 2005, Defendant Wiggans stated that changes to the Company's distribution service agreements in 2004 allowed the Company to have "considerably more information about the inventory levels and channel distribution by the wholesalers" and the Company was "monitoring the shelf life of existing product as it moves through the distribution channel going forward." Moreover, Defendant Wiggans stated the Company contractually prohibited distributors from purchasing excess product. Based on the foregoing, only Connetics could cause the Company's distributors to have excess inventory.

162. Throughout the Class Period, in each of the Company's Form 10-Ks filed with the SEC, Defendants told investors: "We try to maintain inventory levels that are no greater than necessary to meet our current projections." This was not true, as set forth below, as the Defendants repeatedly shipped excess inventory to distributors in order to report forecasted earnings.

3. Defendants Intentionally Ship Excess Product To Distributors To Meet Short-Term Earnings Expectations In Violation Of GAAP

163. Lead Plaintiff's investigation has revealed that, throughout the Class Period, Connetics systematically engaged in a practice known as "channel-stuffing." Channel-stuffing is a fraudulent business practice whereby a company artificially inflates its sales and revenue by intentionally "selling" more of its products to customers than what the retail marketplace demands. By channel-stuffing, a company can temporarily increase its accounts receivables and revenue, but only at the cost of long-term sustainability and accurate financial statements.

Channel-stuffing defrauds investors because, by so doing, a company books sales in the near term at the expense of future periods, which distorts the true state of the company's finances. Further, if the "sales" of products to customers are subject to a right of return or potential rebates, as Connetics' products were, then substantial portions of the shipments may not qualify as "sales" at all, and reporting them as such renders the Company's financial statements materially false and misleading in violation of GAAP.

164. Given the structure of the marketplace and the manner in which Connetics recognized revenue for sales of its products, it was important for Connetics to accurately estimate future retail demand so that it shipped the appropriate amount of product to its distributors. In particular, it was critical that the Company's distributors did not become "overstocked" with excess inventory. If distributors carried excess inventory of Connetics' products, it would, among other things, mean that (1) the distributors would be less likely to purchase additional product in the future, thus making it difficult for the Company to legitimately meet its sales and earnings goals in subsequent financial periods, and (2) there would be a materially higher chance that the distributors would eventually return large amounts of unsold product to Connetics for a full refund and/or become eligible for volume and other discounts at a far higher rate than the Company's historical experience would suggest (as discussed in more detail below).

165. In an effort to estimate the future demand for its products and purportedly to avoid overstocking its distributors, throughout the Class Period, Connetics would prepare regular "forecast" reports that were reviewed by Connetics' senior management. Lead Plaintiff's investigation into Connetics' forecasting process has revealed, for instance, the Company's forecasts considered several factors, including competitor sales, historical sales experience, and the number of prescriptions written and filled for particular products in given periods. The number of prescriptions filled and written for a particular product in any given time period were particularly useful metrics for estimating the retail sales of the product and anticipating the future retail demand.

166. Nonetheless, according to CW3, a National Account Director in charge of Sales Operations, the amount of products shipped (and therefore "sold") to distributors during the Class

Period regularly exceeded the number of prescriptions that were being written for the products. According to CW3, the Company "always met its Wall Street numbers," but never meet its internal goals for prescriptions written. Also according to CW3, Defendants Wiggans and Vontz were repeatedly told during the Class Period that the amounts of product being shipped greatly exceeded the known data about the number of prescriptions written. However, rather than react to this with the concern of honest executives, Wiggans and Vontz purportedly did not want to hear about it and instead directed that **even more** product be put into the channel in order to make Wall Street's numbers.

167. According to CW3, the Company's announcement that it had to restate was not a surprise to anyone in the Company because, according to CW3, the Company was falsely reporting its numbers. According to CW3, "the numbers have never been real from day one" and the Company was "not honest with the public." According to CW3, the Company was insistent on meeting Wall Street numbers regardless of prescription demand for its products – meaning excess inventory was being shipped to distributors.

168. According to CW3, distributors agreed to take excess product from Connetics because it was in their best interest. According to CW3, the Company's prices for drugs were increasing by as much as 15-18% twice a year. Distributors wanted to be able to buy at the lower price and then pass on the price increase to pharmacies. Distributors had nothing to lose by accepting excess product because, according to CW3 and according to the Company's own stated policies, expired product could be returned for an amount in excess of the **initial** purchase price.

169. Lead Plaintiff's investigation has also revealed that, throughout the Class Period, Defendants Wiggans, Higgins and Vontz deliberately manipulated Connetics' forecasting process to justify selling more product into the distribution channel than was needed to meet retail demand. According to CW4, who was directly involved in the forecasting process for more than three years (including throughout the Class Period), CW4 would assist in the preparation of the Company's initial annual forecasts and present them to, among others, Defendants Wiggans, Higgins and Vontz in October of each year. These facts were corroborated by CW3, who was

also directly involved in the forecasting process and attended the annual October meetings throughout the Class Period.

170. Following the initial October meeting with Defendants Wiggans, Higgins and Vontz, Connetics would hold monthly forecast meetings that were attended by, among others, CW4, CW3 (for certain meetings) and Defendants Wiggans, Higgins and Vontz. At these monthly meetings, the forecast reports would be compared to the actual demand for the product as measured by factors including the number of prescriptions filled and written for the product during recent periods. Lead Plaintiff's investigation has revealed that Defendants Wiggans, Higgins and Vontz would regularly direct employees to increase the forecasts so that the Company could internally justify selling more products to distributors than a good-faith estimate of the future retail demand would permit. For instance:

(i) Wiggans regularly instructed CW4 throughout the Class Period to increase the forecasts so that they were in line with Wall Street's expectations for Connetics' future sales.

(ii) When CW4 presented the initial forecast for 2005 to certain members of the Executive Committee (including Wiggans, Higgins and Vontz), CW4 was scolded by Wiggans, who told CW4 that Wiggans had made it clear what the forecast had to be in order to meet Wall Street's expectations, and that the forecast was too low. Wiggans – in the presence of Vontz and Higgins – directed CW4 to increase the forecast so that it met Wall Street's expectations for Connetics' sales.

(iii) CW3 corroborated CW4's assertion that employees were forced to change forecasts without justification and in order to obtain preordained results. According to CW3, at meetings attended by CW3, CW4 would be directed by Wiggans to change the hypotheses in the forecasts until the forecasts matched Wall Street's numbers.

(iv) According to CW4, certain employees became so concerned about the pressure to constantly alter the forecasts without a legitimate business justification that they started keeping "CYA" folders to document certain activities that the employees did not feel comfortable with. One employee involved with the forecasting process maintained a "CYA" file that contained **ninety-three** different iterations of the forecast that Defendants Wiggans, Higgins and Vontz

required him to make in order to purportedly justify increasing the forecasts to meet Wall Street's expectations.

171. In addition to the orders that Defendants Wiggans, Higgins and Vontz gave to Connetics' employees to make improper increases to Connetics' internal forecasts, Lead Plaintiff's investigation has revealed additional facts showing deliberate shipments of excess inventory at quarter end. These include the facts that, according to CW3:

(i) A Connetics' employee who was concerned about the Company's channel-stuffing practices documented e-mails from Defendant Vontz, which instructed the employee to contact distributors at the end of certain quarters during the Class Period and pressure them to take more product than the Company knew was justified.

(ii) The amount of product Connetics shipped to wholesalers consistently did not match the demand for the product, and during the last two weeks of **each quarter** during the Class Period, at the direction of Wiggans, Higgins and Vontz, Connetics would ship significant amounts of additional and unnecessary inventory for the sole purpose of meeting or exceeding Wall Street's expectations for the Company's sales and revenue for that period.

172. The fact that these channel-stuffing practices were fraudulent efforts to mislead Connetics' investors is further confirmed by numerous additional former Connetics employees. For instance, according to CW7, a former Senior Vice President in the sales department who worked at the Company for nearly three years before leaving in late 2005, Defendants Wiggans and Vontz would consistently direct more product to be shipped to wholesalers than was needed to satisfy the demand. According to CW3, Wiggans, Higgins and Vontz were each aware that inventory levels at distributors were excessive throughout the Class Period, but refused to take meaningful steps to reduce inventory to appropriate levels (which, of course, would have required reducing Connetics' sales and revenue as well). According to CW8, a former Territory Manager, there were discussions among Connetics' employees that Connetics had overstocked with distributors. In addition, CW8 corroborated the information provided by the other confidential witnesses in that Connetics would always hit its Wall Street numbers, even though Connetics' internal sales force would never hit its internal goals for number of prescriptions

written. Lead Plaintiff also contacted CW9, who was a Vice President of Sales after the Class Period, and CW9 stated that it was obvious that, during the Class Period, the forecast reports would be "changed on a whim," and were often changed on the whims and at the direction of Wiggans and Vontz. According to CW10, a Regional Sales Director for Connetics from 2003 through November 2005, there seemed to "always be way too much" inventory with Connetics' distributors. Indeed, according to CW10, the Company instituted a special initiative for its sales representatives in August 2005, which management called "Summer Sizzle", specifically intended to redistribute inventory from distributors to pharmacies.

173. According to CW11, a Territory Manager who worked for Connetics for more than six months in 2005, it was made clear at sales meetings attended by CW11 in 2005 that prescription levels were not increasing fast enough to offset the buildup of excess inventory with wholesaler distributors. At these sales meetings, it was also made clear that if Connetics had to accept the excess inventory back as a return (if, for instance, it expired before doctors wrote prescriptions for it), then Connetics would take a "big financial hit." According to CW11, it was a common belief within the Company – and particularly among the sales representatives – that Connetics had overloaded its wholesalers in order to increase its quarterly earnings, and it was unrealistic for Connetics to expect to sell all of the product that was building up in the wholesale inventory. CW11 corroborated the information provided by the other confidential witnesses in that "nobody could understand what was going on" because prescription totals never matched the amount of product being shipped to distributors even though Connetics' Wall Street numbers always "looked good." Like CW10, CW11 recalls the "Summer Sizzle" promotion to move inventory out of distributors' shelves to avoid the Company having to provide the distributors with refunds for expired product. Sales representatives were encouraged to spend money on gifts and do whatever it took to get doctors to write prescriptions and move product out of distributors' warehouses.

174. Defendants Wiggans, Higgins and Vontz were able to perpetrate their fraudulent scheme throughout the Class Period in part because, according to several former Connetics' employees, they "ruled through fear" by creating an atmosphere of intimidation where they

constantly threatened to terminate employees who displeased them. According to CW3, although there were some "heated discussions" among the lower-level employees who were directed to change the Company's forecasts, this was mostly "water cooler discontent" because these employees knew that they would be fired if they challenged Wiggans or Vontz. According to CW4, employees lived in constant fear of being terminated and the senior executives regularly expressed a willingness to terminate employees who did not please them.

175. Connetics' intentional channel-stuffing throughout the Class Period caused Connetics' accruals for rebates, chargebacks and returns to be materially understated, which, in turn, materially overstated the Company's earnings and caused its publicly-filed financial statements to violate GAAP. By injecting excessive inventory into the distribution channel, Connetics and the Insider Defendants knew or should have known that significant amounts of Connetics' products would remain unsold through the expiration date and, therefore, would be returned to Connetics. Likewise, as the Insider Defendants and Connetics knew or should have known, as Connetics deliberately shipped excess product into the distribution channel, it rendered the Company's estimates of anticipated rebates and chargebacks artificially low because, among other reasons, the Company continued to estimate future rebates based on historical experience, without adjusting for the fact that significant amounts of additional product were now in the pipeline (thus rendering historical experience an unreliable indicator of future returns).

176. Connetics could not stuff the channel and understate reserves forever. As Connetics' product languished in distributor and pharmacy inventory for longer periods, inventory got older and the risk of customers returning larger amounts of expired or nearly-expired product grew substantially. The Company was forced to slash shipments to distributors at the end of 2005 and in the beginning of 2006 to decrease distributor inventory levels. Then, as discussed below, in mid-2006, the SEC launched an investigation, and the Insider Defendants and Connetics were forced to restate Connectics' financial statements.

4. Connetics Announces Its Intention To Restate Its Financial Statements

177. On May 3, 2006, Connetics announced in a Form 8-K and accompanying press release filed with the SEC that the Company's "financial statements for the year ended

December 31, 2005, and potentially additional periods, **should no longer be relied upon**." (5/3/06 8-K at 1.) The press release announced that:

> The Company records quarterly reserve provisions for rebates by estimating rebate liability for product sold taking into consideration a number of factors including timing and terms of managed care contracts, time to process rebates, product pricing, sales volumes, units held by distributors and prescription trends. Upon review, the Company has concluded that the rebate rates and method used to calculate the rebate liability in prior periods did not fully capture the impact of these factors, and estimates that the cumulative impact of the change as of December 31, 2005 is approximately $8.0 million to $9.0 million.

Id. This press release also announced that it was "highly likely" that Connetics had material weaknesses in its internal controls over financial reporting.

178. In reaction to this news, the price of Connetics' common stock, which had closed at $15.27 per share on May 2, 2006, traded as low as $13.43 per share on May 4, 2006, a drop of approximately 12%, on heavy trading volume.

179. This announcement, however, failed to disclose Connetics' fraudulent channel-stuffing practices discussed herein, and also failed to disclose the full effect of those practices on the Company's prior financial statements and future financial performance.

180. Indeed, the Insider Defendants and Connetics continued to intentionally mislead investors on these points. For instance, Connetics attempted to allay investor concerns by issuing adjusted financial guidance for fiscal year 2006 of revenues between $211 million and $217 million and diluted EPS between $0.44 to $0.50. In order to convince investors that the adjusted guidance was complete and accurate, on a conference call held May 3, 2006, Defendants Wiggans and Vontz expressly assured investors that the new financial guidance **took into account any future efforts to reduce inventory held at distributors**.

For instance:

(i) Defendant Vontz stated that "any destocking activities over the coming quarters **have been accounted for in our revised guidance given today**,";

(ii) Defendant Vontz stated that "in March we hit five all-time prescription highs for five of our nine product units out there";

(iii) Defendant Wiggans stated "the rebate accounting issue has no effect whatsoever on future trends. And to the degree that we may do destocking over time **that was built into the original guidance**,"; and

(iv) Defendant Wiggans stated "I don't think you'll see any dramatic changes [in inventory levels,] even though our goal is over time to get the inventories down a little bit."

181. On May 22, 2006, Connetics filed a Form 8-K with the SEC that announced that the Company had received a Notice of Delisting due to its failure to file its quarterly report. In reaction to this news, the price of Connetics' common stock, which had closed at $13.26 per share on May 22, 2006, traded as low as $12.51 per share on May 23, 2006, a drop of approximately 6%.

5. The Truth Is Finally Revealed

182. On July 10, 2006, Connetics announced in a Form 8-K and accompanying press release filed with the SEC that:

> [Connetics] expects revenues and earnings per share for the second quarter, and for the full year 2006, to be materially below the amounts included in the guidance that the Company provided on May 3, 2006. **The shortfall in second quarter revenue is due, in part, to the Company's decision to reduce wholesaler inventory by shipping product volumes that were below estimated prescription demand** . . . by shipping less than demand, overall wholesaler inventory levels for the Company's products have been reduced by approximately $7 million, a greater amount than originally planned. **The Company intends to continue to ship below estimated prescription demand during the remainder of 2006, with a goal of further reducing average wholesaler inventory levels to approximately two months on hand by the end of 2006.**

(7/10/06 Press Release at 1.)

183. Analysts covering the Company reacted to this announcement by questioning management's competency and veracity. In a report issued on July 10, 2006, an analyst from CIBC World Markets reported "never say it can't get worse . . . things appear to [be] going from bad to worse at CNCT, where management has withdrawn '06 guidance and 2Q06 results will fall materially short." (7/10/06 CIBC Report at 1.) Another analyst wrote "we are starting to question management's ability to handle the current crises." (7/11/06 Jefferies Report at 1.) Still another analyst wrote:

> There is no way to paint a pretty picture under the various scenarios suggested by yesterday's news . . . it appears **management continues to be less than forthcoming about its accounting issues and the circumstances that have resulted in the revised guidance . . .**
>
> Management [had] indicated its channel inventory was higher than desired on Soriatane, but they had stated that efforts to reduce Soriatane inventory levels

> were incorporated into prior guidance. **Current disclosure suggests inventory levels are a far more severe problem that likely involves all of the company's products.** This also raises questions about how much of this issue results from prior sales to an "international distributor" who may have over purchased in prior periods and is either working down inventory or dumping the excess inventory back into the domestic market. **Either way, management's lack of transparency on the nature and value of the sales to this distributor remains a significant unresolved issue for investors.**

(7/11/06 RBC Report at 1, 2.)

184. In reaction to this news, the price of Connetics' common stock plummeted from a close of $11.69 per share on July 7, 2006 (the immediately preceding trading day), to close at $7.76 per share on July 10, 2006, a drop of approximately 34% on heavy trading volume.

6. The Restatement

185. On July 25, 2006, Connetics filed its Amended Form 10-K/A for fiscal year 2005 (the "Form 10-K/A" or "Restatement") with the SEC.

186. According to GAAP (*see* SFAS 16 and APB Opinion No. 20), accounting restatements are only permitted, and are required, for material accounting errors that existed at the time the financial statements were prepared.

187. In its Restatement, Connetics admitted that its financial statements throughout the Class Period were materially false and misleading. The Restatement stated:

> . . . our previously filed consolidated financial statements should no longer be relied **upon due to errors in the accounting for accruals for estimated rebates and chargebacks for our products**. Because we were already examining revenue reserves in prior years, management decided to apply the same resources to evaluate how we estimate accruals for returns of our products. As a result of our evaluation, we determined that our **methodology for estimating future product returns had contained errors and resulted in an understatement of our returns accruals.**

(10-K/A at 43.) Thus, in the Restatement, Connetics admitted that during the Class Period the Company had materially understated its accruals for estimated product rebates, chargebacks, and the amount of future product returns.

188. Despite the fact that Defendants knew Connetics' distributors had excess inventory that might need to be returned, and that the Company's drug prices had appreciated significantly in each year during the Class Period, Defendants did not properly account for likely returns. Indeed, the Company's Restatement admits:

> **[W]e calculated the value of the estimated units to be returned using the original sales price without taking into account price increases that were implemented between the date of sale through the period of the accrual.** We permit wholesalers to return expired or expiring product for a credit at the then-current sales price less 5%, so the initial sales price may not fully capture our liability for future returns. As a result of our evaluation, we determined that our accrual for product returns had been understated and concluded that the impact of the errors required us to restate our financial statements for prior years.

189. In addition, the Company admitted the restatement was necessary because the Company had failed to consider "all units with potential risk of return" in calculating returns accruals.

190. By restating due to admitted "errors" in its financial statements, Connetics admitted that the Company's financial statements were materially false and misleading at the time they were publicly filed with the SEC. In addition, by restating due to admitted "errors," the Company admitted that it had enough information on hand **at the time it filed its financial statements** to prepare them in accordance with GAAP, but it improperly ignored the available information. (*See id*. (reporting a "correction of an error" involves "**the oversight or misuse** of facts that existed at the time the financial statements were prepared" as opposed to a "change in accounting estimate," which results from "new information or subsequent developments and accordingly from better insight or improved judgment").)

191. In addition, Connetics has also admitted that, throughout the Class Period, the Company suffered from undisclosed material weaknesses in its internal controls over financial reporting. A material weakness in internal controls "is defined as a significant deficiency or a combination of significant deficiencies which results **in more than a remote likelihood that material misstatement of our annual or interim financial statements would not be prevented** . . . ." (7/25/06 10-K/A at 68.) These undisclosed material weaknesses, which stemmed from poor methodologies and lack of oversight of the Company's system for accruing rebates, chargebacks and product returns as well as a lack of involvement of trained employees, allowed the financial statement fraud at Connetics to continue undetected throughout the Class Period, and allowed the Insider Defendants and Connetics to perpetrate their fraudulent scheme unbeknownst to investors.

192. The Company's amended 2005 Form 10-K filed with the SEC after the Class Period includes an "Explanatory Note" describing the basis for the Company issuing restated financial results and Note 2 to the amended financial statements further explains the basis for the restatement. Nowhere in Note 2 nor in the "Explanatory Note" is there any indication the Company restated its financial results because it had obtained inaccurate or otherwise unreliable information from any source concerning inventory levels at the Company's distributors. Rather, the "Explanatory Note" and Note 2 attribute the necessity for restating financial results entirely upon facts known to the Company at the time the prior financial statements were prepared. Elsewhere in the amended 2005 Form 10-K under the heading "Risk Factors", the Company asserts it received inventory level reports with inaccuracies and inconsistencies that made them unreliable – but the amended 2005 Form 10-K does not assert that inventory reports from distributors either understated inventory levels or had anything to do with the Company's need to restate prior financial results. Moreover, the amended 2005 Form 10-K suggests that the Company was made aware of inflated inventory reports via distributors' inventory reports no later than December 2005, but yet the Company failed to properly adjust its reserves at that time and waited until May 2006 to inform investors that they should not rely on the Company's prior published financial statements.

7. Impact On Financial Statements

193. The result (indeed, the goal) of understating the Company's estimated liability for future rebates, chargebacks and returns was to materially overstate the Company's reported net revenues, net product revenue, income from operations, net income, product-related accruals and stockholders' equity during the Class Period. The impact that these financial manipulations had on Connetics' financial statements is set forth in the following charts.

Year Ended December 31, 2005 (In Millions)		
Line Item	**As Reported**	**As Restated**
Net Revenue	$184.2	$176.3
Net Product Revenue	$183.3	$175.4
Income from Operations	$23.8	$15.9
Net Income	$33.9	$26.1
Product-Related Accruals	$24.2	$35.4
Stockholders' Equity	$110.7	$99.9

Year Ended December 31, 2004 (In Millions)		
Line Item	**As Reported**	**As Restated**
Net Revenue	$144.4	$143.2
Net Product Revenue	$142.0	$140.9
Income from Operations	$22.0	$20.8
Net Income	$19.0	$17.9
Product-Related Accruals	$18.4	$21.6
Stockholders' Equity	$127.9	$124.8

194. As a result of these material misstatements, for the full fiscal year ended December 31, 2005, Connetics' Net Revenue was overstated by 4.7%, Net Product Revenue by 5%, Income from operations by 34%, Net Income by 24%, and Stockholders' Equity by 10%, while Product-Related Accruals were understated by 32%.

195. As set forth in the Restatement, the breakdown of the material misstatements in Connetics' financial statements for each quarter of 2005 is as follows:

Fiscal 2005 Quarters (In Millions)		
	As Reported	**As Restated**
First Quarter 2005		
Net Revenue	$42.3	$40.3
Net Product Revenue	$42.1	$40.2
Income from Operations	$1.5	($0.5)
Net Income	$1.0	($1.0)
Second Quarter 2005		
Net Revenue	$45.3	$45.3
Net Product Revenue	$45.2	$45.3
Income from Operations	$2.6	$2.7
Net Income	$2.5	$2.6
Third Quarter 2005		
Net Revenue	$55.3	$50.9
Net Product Revenue	$55.1	$50.7
Income from Operations	$15.6	$11.2
Net Income	$15.3	$10.9
Fourth Quarter 2005		
Net Revenue	$41.1	$39.5
Net Product Revenue	$40.7	$39.0
Income from Operations	$4.0	$2.4
Net Income	$15.0	$13.4

196. As set forth in the Restatement, the breakdown of the material misstatements in Connetics' financial statements for each quarter of 2004 is as follows:

Fiscal 2004 Quarters (In Millions)		
	As Reported	**As Restated**
First Quarter 2004		
Net Revenue	$24.9	$24.5
Net Product Revenue	$23.5	$23.1
Income from Operations	$2.4	$1.9
Net Income	$1.8	$1.4
Second Quarter 2004		
Net Revenue	$38.2	$38.6
Net Product Revenue	$37.9	$38.6
Income from Operations	$8.7	$9.1
Net Income	$7.5	$7.8
Third Quarter 2004		
Net Revenue	$37.3	$37.1
Net Product Revenue	$36.9	$36.7
Income from Operations	$4.2	$3.9
Net Income	$3.7	$3.4
Fourth Quarter 2004		
Net Revenue	$43.7	$42.8
Net Product Revenue	$43.5	$42.6
Income from Operations	$6.7	$5.7
Net Income	$6.0	$5.1

8. GAAP Violation

197. Throughout the Class Period, Connetics represented that its financial statements were in conformance with GAAP. These representations were false. As set forth herein, the financial statements issued by the Company for fiscal years 2004 and 2005, and the financial statements for the fiscal quarters therein, did not fairly and accurately represent the Company's financial position and the results of its operations because they violated key provisions of GAAP.

198. GAAP principles are the official standards accepted by the SEC and promulgated in part by the American Institute of Certified Public Accountants ("AICPA"). GAAP consists of

a collection of authoritative literature, including the Financial Accounting Standards Board ("FASB") Statements of Financial Accounting Statements ("SFAS"), FASB Interpretations ("FIN"), Accounting Principles Board Opinions ("APB Opinion"), AICPA Accounting Research Bulletins ("ARB"), and Emerging Issues Task Force ("EITF") guidance. SEC Regulation S-X (17 C.F.R. §210.4-01(a)(1)) provides that financial statements filed with the SEC that are not prepared in accordance with GAAP will be presumed to be false or misleading.

199. Connetics was required under GAAP to estimate the amount of any rebates, chargebacks and anticipated reserves and establish a reasonable reserve against revenues to account for them. (*See* FASB Statement No. 5 (sales revenue and cost of sales reported in the income statement shall be reduced to reflect estimated returns).)

200. With respect to recording accruals and reporting sales subject to a right of return, in order to comply with GAAP, Connetics had to adhere to SFAS 48, "Revenue Recognition When Right of Return Exists." SFAS 48 provides:

> 6. If an enterprise sells its product but gives the buyer the right to return the product, revenue from the sales transaction shall be recognized at time of sale only if all of the following conditions are met:
>
> a. The seller's price to the buyer is substantially fixed or determinable at the date of sale.
>
> b. The buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product.
>
> c. The buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product.
>
> d. The buyer acquiring the product for resale has economic substance apart from that provided by the seller.
>
> e. The seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer.
>
> f. The amount of future returns can be reasonably estimated. **Sales revenue and cost of sales that are not recognized at time of sale because the foregoing conditions are not met shall be recognized either when the return privilege has substantially expired or if those conditions subsequently are met, whichever comes first**.

201. Thus, in order to comply with SFAS 48, Connetics had to be able to "reasonably estimate" its amount of future returns. If Connetics was unable to do so, then under GAAP, Connetics could not recognize any revenue on the sale of the products until the right of return expired. Because Connetics' return policy allowed for products to be returned up to one year **after** their expiration date, and Connetics regularly shipped products that were between ten and fifteen months away from expiration, unless Connetics could "reasonably estimate" future returns, it would not be allowed, consistent with GAAP, to recognize any revenue on products for approximately **two and one-half years** after the products were shipped. This would have been catastrophic to the Company.

202. SFAS 48 also provides guidance on "the ability to make a reasonable estimate of the amount of future returns," and states that the ability to estimate returns may be impaired by a number of factors, including:

> c. Absence of historical experience with similar types of sales of similar products, **or inability to apply such experience because of changing circumstances** . . .

203. As discussed above, Connetics was engaged in a fraudulent channel-stuffing scheme throughout the Class Period. This scheme resulted in significantly greater amounts of inventory being placed into the distribution channel than was appropriate, and it was significantly out of line with Connetics' historical practices. Thus, the scheme resulted in a "changing circumstance" that rendered Connetics' historical returns experience unreliable as a basis to estimate future returns. Nonetheless, Connetics continued to use its historical returns experience (sometimes going back as far as three or four years) to estimate future returns in order to understate its estimated reserves and overstate its revenues. Given the changing circumstances – *i.e.*, channel-stuffing – the Insider Defendants and Connetics knew that historical experience no longer provided a sound basis to make a reasonable estimate of future returns. Nonetheless, in violation of GAAP, the Insider Defendants and Connetics applied the lower rate of "historical" returns to "estimate" future returns – which had the effect of understating the Company's accruals for future returns, and overstating its sales and revenue. This practice violated GAAP and rendered Connetics' financial statements materially false and misleading.

204. With respect to recording accruals and reporting sales subject to rebates and chargebacks, in order to comply with GAAP, Connetics had to adhere to EITF No. 01-9 "Revenue Recognition When Right of Return Exists." EITF No. 01-9 provides:

> The vendor should recognize the rebate or refund obligation as a reduction of revenue based on a **systematic and rational allocation of the cost of honoring rebates or refunds earned and claimed to each of the underlying revenue transactions that result in progress by the customer toward earning the rebate or refund**. Measurement of the total rebate or refund obligation should be based on the estimated number of customers that will ultimately earn and claim rebates or refunds under the offer (that is, breakage should be considered if it can be reasonably estimated). **However, if the amount of future rebates or refunds cannot be reasonably estimated, a liability should be recognized for the maximum potential amount of the refund or rebate (that is, no reduction for breakage should be made)** . . . the following factors may impair a vendor's ability to make a reasonable estimate:
>
> * * *
>
> b. Absence of historical experience with similar types of sales of similar products, **or inability to apply such experience because of changing circumstances** . . .

205. Thus, as with the application of SFAS 48 discussed above, the fraudulent channel-stuffing scheme was a "changing circumstance" that rendered Connetics' historical rebate and chargeback experience unreliable as a basis to estimate future rebates and chargebacks. Nonetheless, throughout the Class Period, Connetics continued to use its historical rebate experience to estimate future rebates and chargebacks. Given the changing circumstances – *i.e.*, channel-stuffing – the Insider Defendants and Connetics knew that historical experience no longer provided a "systematic and rational" basis to estimate future rebates and chargebacks. In violation of GAAP, however, the Insider Defendants and Connetics applied the lower rate of "historical" rebates and chargebacks to determine future estimates – which had the effect of understating the Company's accruals for future returns, and overstating its sales and revenue. They followed this practice in order to ensure that Connetics' revenue and sales met or exceeded Wall Street's expectations. This practice violated GAAP and rendered Connetics' financial statements materially false and misleading.

VI. DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS

206. Prior to and during the Class Period, Defendants (other than Yaroshinsky and Zak) made the following false and misleading statements and omissions.

A. Defendants' Pre-Class Period Statements

207. Prior to the beginning of the Class Period, Defendants made a number of statements concerning the development and capabilities of Velac. Defendants' statements concerning Velac before June 2004 show information in the market when Defendants' issued actionable, false and misleading statements thereafter. Lead Plaintiff does not assert that Defendants' statements violated the federal securities laws with respect to statements concerning Velac before June 2004.

B. Defendants' Actionable False And Misleading Statements And Omissions During the Class Period

208. On January 27, 2004, Connetics issued a press release entitled "Connetics Reports Fourth Quarter EPS of $0.05 on 41% Increase in Product Revenue" (the "January 27, 2004 Press Release"). The January 27, 2004 Press Release reported results for the Fourth Quarter and for the year ended December 31, 2003. It stated:

> "We are proud to report our second consecurtive quarter of profitability, and continued strong gains in product sales and prescription growth for our two marketed products, Olux and Luxiq, said Thomas G. Wiggans…. "Connetics is now a profitable growth company with solid financial performance, significant progress in our product pipeline and a bright future. Looking back over 2003, we had a very successful year, yet just as important, these accomplishments built a solid foundation for continued growth and success," added Wiggans.
>
> The Company expects full-year 2004 product sales to be between $86 million and $492 million, and total revenues to be between $88 million and $96 million. Combined OLUX® and Luxiq® revenue for 2004 are projected to be $82 million to $86 million. Connetics projects combined SG&A and R&D expenses for 2004 to be between $71 million to $73 million. Net Interest expense for 2004 is projected to be $1.0 million to $1.5 million. Diluted earnings per share (EPS) for 2004 are projected to be $0.21 to $0.25, based on an estimated 34.5 million diluted shares and an estimated effective tax rate of 12%[.]

209. As set forth in more detail in Section V.A, the January 27, 2004 statements were materially false and misleading because, among other reasons, as the Company has admitted, Connetics' 2003 financial results understated the Company's revenue reserve for the year-ended 2003 by $167 thousand. The Company's Restatement explained it had to incur "an increase in our revenue reserves of $598,000 to capture additional liability for product returns."

210. On May 4, 2004, Connetics issued a press release entitled "Connetics Reports

First Quarter EPS of $0.05, Product Revenues Increase 65% to $23.6 Million" (the "May 4, 2004 Press Release"). The May 4, 2004 Press Release stated:

> Connetics . . . today reported net income for the first quarter ended March 31, 2004 of $1.9 million, or $0.05 per share on a fully diluted basis. This compares with a net loss for the 2003 first quarter of $5.4 million, or $0.17 per share.
>
> Total revenues for the first quarter of 2004 increased 63% to $25.0 million, compared with total revenues of $15.3 million for the first quarter of 2003. Product revenues for the quarter were $23.6 million, including $19.8 million in sales of OLUX(R) and Luxiq(R), an increase of 39% over sales of $14.3 million for those two products in the first quarter of 2003. In addition, the Company booked $3.6 million in sales of Soriatane(R) during the first quarter of 2004.

211. The May 4, 2004 Press Release also announced Connetics' expected product revenues and earnings growth for 2004:

> Product revenues are now expected to be $126 million to $134 million, with sales of OLUX and Luxiq totaling $87 million to $91 million. This compares with prior guidance for product revenues of $114 million to $122 million, including $82 million to $86 million for OLUX and Luxiq. Total revenues (which include royalties and contract payments) are expected to be $128 million to $137 million . . .

212. The May 4, 2004 Press Release also attached unaudited financial statements for the quarter, which reported the following:

(i) Product Revenues of $23,566,000;

(ii) Revenues of $24,982,000;

(iii) Net Earnings of $1,873,000;

(iv) Basic Net Income per share of $0.06; and

(v) Diluted Net income per share of $ 0.05.

213. On May 4, 2004 Connetics held a conference call with investors that was participated in by, among others, Wiggans, Higgins, Vontz and Krochmal (the "May 4, 2004 Conference Call"). On that call, Defendant Wiggans stated:

> . . . In the first quarter, we recorded record revenues, as the press release stated. Product revenues were up 63 percent over last year, with OLUX and Luxiq revenues up 39 percent. Our earnings per share was a 20 cent improvement – the last year's loss of 17 cents versus a profit of 3 cents this quarter, excluding the gain of 2 cents that John will talk about as a result of our change in manufacturing and product development activities and accounting. So a swing of 20 cents there period-over-period.

214. The May 4, 2004 statements in ¶¶210-213 were materially false and misleading for the reasons set forth above in Section V.B. In particular, Connetics has admitted in its Restatement, that the financial statements for first quarter 2004 were false when made. The May 4 statements reported artificially inflated revenues and sales of products which were the result of the Company shipping excess product to distributors that exceeded product demand in the retail channel. The Company had inadequate reserves for returns of the excess inventory, which inflated reported earnings. Thus, while the Company publically reported a 63 percent increase in product revenues, the reported revenues were the result of the Company stuffing the channels with excess inventory that exceeded the retail demand for the product and understating the reserves for rebates, chargebacks and returns of the excess product.

215. On or about May 10, 2004, Connetics filed with the SEC Connetics' Form 10-Q for the quarter ending March 31, 2004 (the "1Q04 10-Q"). The 1Q04 10-Q was signed and certified by Defendants Wiggans and Higgins. Wiggans and Higgins each certified that "the information contained in the report presents, in all material respects, the financial condition and results of operations of the Company." Also, pursuant to Section 302 of Sarbanes-Oxley, Defendants Wiggans and Higgins each certified that based on his knowledge, "this report does not contain any untrue statement of a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

216. Connetics also represented in the 1Q04 10-Q that Defendants Wiggans and Higgins each confirmed that Connetics' ". . . disclosure controls and procedure were effective in timely alerting them to material information required to be included in our periodic SEC Reports." Wiggans and Higgins also confirmed there had ". . . been no change in [Connetics'] internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting." The certifications signed by Defendants Wiggans and Higgins and attached to the 1Q04 10-Q as exhibits stated that these Defendants were responsible for "establishing and maintaining disclosure controls and procedures . . . and internal control over financial reporting" for Connetics and stated that they had:

> designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; [and]
>
> disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

217. The 1Q04 10-Q stated "we have prepared the accompanying unaudited condensed consolidated financial statements . . . in accordance with accounting principles generally accepted in the United States."

218. The 1Q04 10-Q reported the following results for the fiscal period ended March 31, 2004:

(i) Product Revenues of $23,566,000;

(ii) Revenues of $24,982,000;

(iii) Income from operations of $2,592,000;

(iv) Net Income of $1,873,000;

(v) Basic Net Income per share of $0.06; and

(vi) Diluted Net income per share of $ 0.05.

219. The 1Q04 10-Q also stated "We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, when title has passed, the price is fixed or determinable, and we are reasonably assured of collecting the resulting receivable. We recognize product revenues net of estimated allowances for discounts, returns, rebates, and chargebacks."

220. These statements in the 1Q04 10-Q were materially false and misleading for the reasons set forth above in Section V.B. In particular, Connetics has admitted in its Restatement, that the financial statements for first quarter 2004 were false when made. The reported revenues were the result of the Company's channel-stuffing practices. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP. In addition, the statements regarding the Company's internal controls were materially false and

misleading because, as corroborated by numerous former employees contacted by Lead Plaintiff, the internal forecasts were manipulated and "changed on a whim" with disregard to internal controls in order to meet Wall Street numbers.

221. On July 1, 2004, the *Dermatology Times* issued a report that included information provided by the Company and Defendant Krochmal:

> . . . [T]rial results revealed patients treated with the Velac gel had significantly lower lesion counts, and significantly less acne by investigator assessment, than either clindamycin or tretinoin gel alone.
>
> "The combination is powerful," says dermatologist Lincoln Krochmal, M.D., executive vice president of research and product development for Connetics Corp.
>
> "Together, they do more as a single product than each active by itself . . . **what you have to show in any combination product is that the combined product is superior, and clearly that's what you find here.**"
>
> . . . The manufacturer of Velac recently announced results of two phase 3 trials, and says that a new drug application (NDA) will be submitted to the U.S. Food and Drug Administration (FDA) in the third quarter of 2004.

222. These statements in the July 1, 2004 *Dermatology Times* were materially false and misleading for the reasons set forth above in Section V.A. In particular, these statements were misleading because they were made without disclosure of the results of the Mouse Study and that the Company had been informed by its expert panel that the panel knew of no drug that exhibited a similar result and was approved by the FDA.

223. On July 28, 2004, Connetics issued a press release asserting the Company was on-track to obtaining FDA approval of Velac. The press released quoted Defendant Wiggans: "Looking ahead, we are diligently preparing to initiate two clinical trials while preparing our commercial operations for the introduction of Actiza, Extina and Velac[.]" The press release also stated: "R&D expenses 2004 year-to-date were $9.2 million, down from $17.0 million last year **as pivotal trials** for Extina, Actiza and **Velac were completed in 2003**." The press release further stated: "Connetics projects it will make a $3.5 million milestone payment to Yamanouchi Europe B.V. in the third quarter concurrent with the projected submission of the Velac NDA."

224. On July 28, 2004, Connetics also held a conference call with investors that was

participated in by, among others, Defendants Wiggans, Higgins and Vontz (the "July 28, 2004 Conference Call"). On the July 28, 2004 Conference Call, Defendant Vontz stated ". . . We are working diligently to finalize the NDA submission and are on track to meet that goal of filing that NDA this quarter . . . ."

225. The statements in the July 28, 2004 Press Release and the July 28, 2004 Conference Call were materially false and misleading for the reasons set forth above in Section V.A. In particular, the "pivotal" Velac trials that were purportedly completed would have to be, at the very least, redone by Connetics to demonstrate that Velac was not tumorogenic. Further testing would be costly and time consuming. It was misleading to state the Company was preparing for commercial operations of Velac and the NDA would be submitted in 3Q04 when Defendants knew that Velac would not be approved by the FDA for commercial sales without out further animal testing, which would take at least another six months if not years and would require the Company to hold off on filing the NDA and push back commercial release of Velac.

226. On October 25, 2004, Connetics issued a press release entitled "Connetics Reports Third Quarter Earnings per Share of $0.10; Company Introduces 2004 Fourth Quarter Financial Guidance (the "October 25, 2004 Press Release"). The October 25, 2004 Press Release stated:

> Connetics reported net income for the third quarter ended September 30, 2004 of $3.7 million, or $0.10 per diluted share, which includes a $3.5 million milestone payment due to Yamanouchi Europe B.V. in conjunction with the submission of the Velac(R) New Drug Application (NDA). This compares with net income of $1.6 million, or $0.05 per diluted share, for the third quarter of 2003. Total revenues for the third quarter of 2004 were $37.3 million, compared with total revenues of $19.7 million for the third quarter of 2003. Product revenues for the 2004 third quarter more than doubled to $37.0 million, compared with $17.7 million for the comparable period last year, reflecting growth in revenues of OLUX(R) and Luxiq(R), and the addition of Soriatane(R), which the Company acquired from Roche in March 2004. The Company had cash, cash equivalents and short-term investments on September 30, 2004 of $78.0 million.

227. The October 25, 2004 Press Release quoted Defendant Wiggans as stating:

> I am delighted to report on our progress, particularly our recent regulatory milestones including the FDA approval of Evoclin(TM) and the filing of the NDA for our Velac product . . . . The Company continues to execute well on all fronts, and we are anticipating a strong finish to 2004.

228. On October 25, 2004, Connetics held a conference call with investors that was participated in by, among others, Defendants Wiggans and Vontz (the "October 25, 2004

Conference Call"). On the October 25, 2004 Conference Call, Defendant Wiggans stated "Let me start out by saying the state of the business, we believe, has never been healthier."

229. On the call, Defendant Wiggans also stated:

> It was another solid quarter for us financially. We earned 10 cents, which included the one time charge for the Velac payment versus our first profitable quarter of five cents last year. So far, the business this year has generated $32.6 million in cash flow versus a nine-month year-to-date total at this time last year of a negative $12.7 million in cash flow. So a lot of our expectations, the way we've built this business to become a very important and significant cash flow generator I believe is beginning to materialize as of the third quarter and year to date this year.

230. On the call, Defendant Higgins stated:

> Now I'd like to give guidance for the fourth quarter. We've reflected various numbers in our press release, but specifically I'd like to comment on our product revenue guidance for the fourth quarter we forecast to be $43 to $446 million for our brand . . . . We're very pleased now as we head into the fourth quarter to look at total product revenues for the year of $142 to $145 million.

231. On the October 25, 2004 Conference Call, Defendant Vontz stated that ". . . an important accomplishment in the third quarter for our regulatory team, who completed our largest NDA filing to date with the Velac filing, a tremendous amount of work by our team, very excited that we achieved our goal, and now can await a PDUFA date of June 25th, 2005."

232. On the call, Defendant Vontz also stated:

> Where we will have comparative information, and advantages, though, frankly, is with Velac. The world is changing, as you're probably well aware, with endpoints. The new hurdle that has been imposed in the last 18 months is—for a full acne claim is demonstration of both inflammatory and non-inflammatory resolution of lesions, and that we have in spades with Velac.

233. These statements were materially false and misleading for the reasons set forth above in Section V.A (statements regarding Velac) and Section V.B (statements regarding reported financial performance). In particular, Connetics has admitted in its Restatement, that the financial statements for third quarter 2004 were false when made. The statement that the "Company continues to execute well on all fronts" was misleading because the Company deliberately shipped excess product to distributors and understated reserves in order to meet Wall Street expectations. The statement regarding the Velac NDA was misleading because the Company failed to disclose that its expert panel advised Connetics that they were aware of no

drug exhibiting a "positive dermal" such as Velac that had ever been approved by the FDA. It was misleading to assert the Company completed an NDA filing for Velac that could be approved by the PDUFA date, as explained at ¶¶95-100, Defendants knew the positive Mouse Test meant the FDA would – at the very least – require the Company to run additional testing to demonstrate that Velac was not a carcinogen and that this additional testing would push out approval by many months if not years. It was also misleading to promote the efficacy of Velac's "inflammatory and non-inflammatory resolution of lesions" without disclosing the safety concerns in the vehicle that were revealed in the Mouse Study.

234. On or about November 8, 2004, Connetics filed with the SEC Connetics' Form 10-Q for the quarter ending September 30, 2004 (the "3Q04 10-Q"). The 3Q04 10-Q was signed and certified by Defendants Wiggans and Higgins in a manner identical, or nearly identical, to the statements made in ¶¶215-217.

235. The 3Q04 10-Q reported the following results for the three month period ended September 30, 2004:

(i) Product Revenues of $36,999,000;

(ii) Revenues of $37,344,000;

(iii) Income from operations of $4,212,000;

(iv) Net Income of $73,695,000;

(v) Basic Net Income per share of $0.10; and

(vi) Diluted Net Income per share of $0.10.

236. The 3Q04 10-Q also stated ". . . We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, when title has passed, the price is fixed or determinable, and we are reasonably assured of collecting the resulting receivable. We recognize product revenues net of estimated allowances for discounts, returns, rebates, and chargebacks."

237. These statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, Connetics has admitted in its Restatement, that the financial statements for third quarter 2004 were false when made. In particular, these statements reported artificially inflated revenues which were the result of the Company shipping excess product to

distributors that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP.

238. On January 25, 2005, Connetics issued a press release entitled "Connetics Reports Fourth Quarter EPS of $0.17 and Product Revenues up 128% to $43.5 Million; Concludes First Year of Profitability with $0.52 EPS (the "January 25, 2005 Press Release"). The press release stated in part:

> Connetics . . . reported record net income for the 2004 fourth quarter of $6.4 million, or $0.17 per diluted share, compared with $1.5 million, or $0.05 per diluted share, for the comparable quarter last year… Connetics expects 2005 total revenues to be between $190 million and $200 million, representing an increase of 32% to 39% compared with 2004. Diluted EPS for 2005 is projected to grow by approximately 70% and to be in the range of $0.88 to $0.92.

239. The January 25, 2005 Press Release quoted Defendant Wiggans as stating:

> Strong product revenue growth during 2004 contributed to our first full year of profitability and the fifth consecutive year of growth in our core brands OLUX and Luxiq . . . .

240. On January 25, 2005, Connetics held a conference call with investors that was participated in by, among others, Defendants Wiggans, Higgins and Vontz (the "January 25, 2005 Conference Call"). On the January 25, 2005 Conference Call, Defendant Wiggans stated: ". . . 2004 was a substantial growth and expansion year for the Company. Not only did we post significant revenue growth and turn profitable, the expanded revenue, income, and cash flow, especially from Soriatane, allowed us to substantially expand our business and increase our commercial presence in the dermatology market."

241. On the call, Defendant Wiggans also stated:

> . . . We have excellent data on Velac. We now have an expanded and very talented sales force. And we are confident that we will be successful in this market with our acne franchise, and in particular, with Velac . . . . We see it again in '05 as we forecast approximately a 35 percent increase in revenues and approximately a 70 percent increase in earnings. And we expect this to continue, if not accelerate, as we go into 2006. Our ability to deliver innovative product development and substantial sales growth through a relatively modestly expanding organization remains a key part of our business model. And we continue to deliver on this . . . . In summary we believe our business plan continues to be one of the most attractive in the specialty pharmaceuticals sector. Our expanded sales force and increasing commercial presence; our ongoing product development model, delivering innovative new products and innovative

> new technologies for dermatologists and their patients—we believe will continue to generate substantial revenue, income, and value growth for our shareholders...

242. On the January 25, 2005 Conference Call, Defendant Higgins stated:

> And our acne products – Evoclin, which we just launched, **and Velac, we expect to be launched midyear**, making up the balance or roughly 20 percent of our sales. That amount for our acne franchise in 2005 we expect to be split roughly 50-50 between both Evoclin and Velac . . . . **In 2006, we forecast enjoying a full year of Velac sales**.

243. On the call, Defendant Vontz stated with regard to Velac:

> **[W]e know a lot about our product** and . . . **we're very confident in the data set that we've got.** We believe it's **one of the strongest data sets for an acne product submitted to the FDA**. And we're obviously **very excited to launch it**.
>
> * * *
>
> I have a lot of confidence in the strength of our data.

244. On the call, Defendant Higgins stated that with regard to 2005 revenues:

> So our guidance—when we give total revenue guidance of 190 to 200 million, that is principally all product revenue. As I indicated, we are looking at our acne product comprising approximately 20 percent of that revenue guidance, split fairly equally between Evoclin for a full year and Velac for a partial year.

245. These statements were materially false and misleading for the reasons set forth above in Section V.A (statements regarding Velac) and Section V.B (statements regarding reported financial performance). The statements regarding financial performance were materially false and misleading because Defendants knew the Company was channel stuffing and understating reserves to meet its numbers. In its Restatement, Connetics has admitted that its financial results for the fourth quarter 2004 were false when made. Regarding Velac, it was materially false and misleading for Defendant Wiggans to state that the Company had "excellent data on Velac" when the Company knew since June 2004 that Velac, with its patented vehicle, has significant safety concerns. It was also materially false and misleading to assert the Company would launch Velac mid-year and misleading to include Velac in the revenue guidance. As explained at ¶¶95-100, Defendants knew the positive Mouse Test meant the FDA would – at the very least – require the Company to run additional testing to demonstrate that Velac was not a carcinogen and that this additional testing would push out approval by many months if not years. It was also materially false and misleading to project large revenues for the product while

concealing the results of the FDA-required laboratory study indicating that Velac was carcinogenic and that the Company had been informed by an expert panel that the panel knew of no drug that exhibited a similar result and was approved by the FDA. In addition, Vontz's statement that Velac was one of the strongest data sets for an acne product was materially false and misleading because Defendants had actual knowledge of the results of the undisclosed Mouse Study and knew of no other drug with similar results that had been approved by the FDA.

246. On March 16, 2005, Connetics filed with the SEC its annual report on Form 10-K for the year ended December 31, 2004 (the "2004 10-K"). The 2004 10-K was signed by Defendants Wiggans and Higgins. The 2004 10-K was signed and certified by Defendants Wiggans and Higgins consistent with the statements in ¶¶215-216.

247. The 2004 10-K reported the following results for the fiscal year ended December 31, 2004:

(i) Product Revenues of $142,059,000;

(ii) Revenues of $144,355,000;

(iii) Income from operations of $21,983,000;

(iv) Net Income of $19,015,000;

(v) Basic Net Income per share of $0.54; and

(vi) Diluted Net income per share $ 0.51.

248. The 2004 10-K also stated:

> We recognize product revenue net of allowances for estimated discounts, returns, rebates and chargebacks. We allow a discount for prompt payment. We estimate these allowances based primarily on our past experience. We also consider the volume and price mix of products in the retail channel, trends in distributor inventory, economic trends that might impact patient demand for our products (including competitive environment), and other factors.
>
> We accept from customers the return of pharmaceuticals that are within six months before their expiration date. As a practice, we avoid shipping product that has less than ten months dating. We authorize returns for damaged products and exchanges for expired products in accordance with our returned goods policy and procedures. **We monitor inventories in the distributor channel to help us assess the rate of return**.

249. These statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, Connetics admits in its Restatement that the financial

statements for year ending December 31, 2004 were false when made. These statements reported artificially inflated revenues which Defendants knew were the result of the Company shipping excess product to distributors that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP. In addition, as corroborated by numerous former employees contacted by Lead Plaintiff, the internal forecasts were manipulated and "changed on a whim" with disregard to inventory levels in order to meet Wall Street numbers.

250. The 2004 10-K also stated:

> We concluded clinical trials in 2004 and subsequently submitted an NDA with the FDA for our product candidate Velac, a combination of 1% clindamycin, and 0.025% tretinoin in a gel formulation, for the potential treatment of acne vulgaris. The FDA accepted the Velac NDA for filing in October 2004 with a filing date of August 23, 2004.
>
> In December 2002, we intitiated the Phase III program for Velac, a first-in-class combination of 1% clindamycin and 0.025% tretinoin, for the treatment of acne. The Velac clinical program consists of two pivotal trials designed to demonstrate superiority to the individual drug products, and two smaller supplemental clinical studies required by the FDA. We completed enrollment of both pivotal trials in late 2003, enrolling over 2,200 patients. In March 2004, we announced the positive outcome of the Phase III clinical trials of Velac. The data from each trial demonstrated a consistently robust and statistically superior treatment effect for Velac compared with clindamycin gel, tretinoin gel and placebo gel on both of the primary endpoints. An analysis of the combined data from the clinical trials demonstrated similar results to the individual trials. **The data from these trials also demonstrated that Velac was safe and well tolerated**, with the most commonly observed adverse effects being application site reactions such as burning, dryness, redness and peeling. Following this positive clinical outcome, we submitted an NDA with the FDA for Velac in August 2004. The NDA was accepted for filing by the FDA in October 2004 with a filing date of August 23, 2004 and a user fee goal date of June 25, 2005. If approved by the FDA, we believe Velac will compete with topical retinoids as well as topical antibiotics, representing approximately $988 million in U.S. prescriptions during the 12 months ended December 2004. Prescriptions for the entire U.S. acne market during that same period were approximately $1.2 billion not including oral antibiotics.

251. These statements were materially false and misleading for the reasons set forth above in Section V.A. It was misleading to make the statement that Velac was "safe and well tolerated" while failing to disclose the results of the Mouse Study showing that the patented vehicle in Velac, which was supposed to stabilize the combination of clindamycin and tretinoin,

failed the pre-clinical Tg.AC Mouse Study. Defendants' statements were misleading because it implies that the adverse effects were limited to reactions at the same level of magnitude as "burning, dryness, redness and peeling" without disclosing that pre-clinical tests showed that Velac was a carcinogen. It was also misleading to assert the Company would obtain FDA approval by the PDUFA date because, as explained at ¶¶95-100, Defendants knew the positive Mouse Test meant the FDA would – at the very least – require the Company to run additional testing to demonstrate that Velac was not a carcinogen and that this additional testing would push out approval by many months if not years.

252. On March 30, 2005, The Buckingham Research Group issued an analyst report written by David G. Buck in which he reported on his conversations with Defendant Higgins. The report stated: "We recently spent a day meeting with Connetics' Executive Vice President and CFO, John Higgins. . . ." As a result of Defendant Higgins' statements during that meeting, Mr. Buck wrote: "For Velac, the Company and we remain confident that this represents a peak sales opportunity of $150 million or greater and **the Company has high confidence in an outright FDA approval by June 25th 2005**." Defendant Higgins' and the Company's statements were false and misleading for the reasons set forth in Section V.A. It was misleading to assert the Company was highly confident it would obtain FDA approval by the PDUFA date because, as explained at ¶¶95-100, Defendants knew the positive Mouse Test meant the FDA would – at the very least – require the Company to run additional testing to demonstrate that Velac was not a carcinogen and that this additional testing would push out approval by many months if not years.

253. On April 14, 2005, (the day after Defendants had a conference call with the FDA concerning Velac as set forth in ¶¶111-114) Connetics hosted their annual 2005 Analyst and Investor Day in New York City.

254. During the Company's Analyst and Investor Day, which was available via webcast and was attended by numerous analysts, Defendants increased the Company's 2005 revenue guidance (which included revenues from sales of Velac). In a press release issued on April 14, 2005, the Company stated:

> Outlining the Company's Long-Term Goals: Connetics' Chief Executive Officer, Thomas G. Wiggans, outlined the Company's long-term growth goals and put them in the context of a rapidly growing medical dermatology market. "Connetics is building the premier U.S. medical dermatology company through best-in-class technology and product innovation, strong commercial capabilities, outstanding customer service and excellent execution," said Wiggans. "This market will grow from $3.6 billion in 2000 to a projected $6 billion by 2010. We have aggressive plans to capture an increasing share of this market, and we have set a goal to achieve annual product revenues of $750 million by the end of the decade. This includes more than $500 million in annual revenues from products that we currently market or are already in our development pipeline."
>
> Revising 2005 Revenue Guidance Upward: **Connetics is now projecting 2005 total revenue will be between $195 million and $206 million, up from prior guidance of $190 million to $200 million,** which represents an increase of 35% to 42% compared with 2004 total revenue.

255. In addition, during the Analyst and Investor Day, Defendants made favorable presentations concerning Velac without disclosing the fact that, just the day before, they had been told by the FDA it had serious concerns about the safety of Velac.

256. After attending the Analyst and Investor Day, numerous analysts reported on Defendants' false and misleading statements. For example, on April 14, 2005, CIBC issued a report repeating Defendants' false and misleading statements from the Analyst Investor Day stating:

> Analyst Day Highlights; All Eyes On Velac
>
> * * *
>
> **The Company is positioned on the verge of launching its first potential $100MM therapeutic, Velac, with FDA approval anticipated mid-year**.
>
> * * *
>
> Connetics provided additional clinical info on Velac, its next potential new product launch currently undergoing FDA review with a targeted action date of June 25, 2005. Velac is a potential first-in-class combination formulation of the retinoid isotretinoin 0.025% and the antibiotic clindamycin 1% that will compete in a $1B combined market for these agents as stand-alone products. The company disclosed that both of its pivotal phase III trials achieved statistical significance (95% confidence level) on the primary endpoint of ISGA (Investigator Static Global Assessment) on all three arms of the trial – vs. placebo, clindamycin and isotretinoin as single agent therapy.

257. On April 15, 2005, The Buckingham Research Group issued a report repeating Defendants' false and misleading statements from the Analyst Investor Day stating:

> **The Company appeared enthusiastic in the R&D overview about the Velac studies**, two pivotal trials involving 1,136 patients (study #304) and 1,083

> patients (study #305) respectively. The Velac studies met primary endpoints on both the ISGA (investigator global assessment) and lesion count measurements and we expect this combination acne drug to receive an outright approval on June 25th. While Connetics did not say so directly, it also appears to be confident in approval. The Velac combination acne drug represents a $150 million peak sales drug in our view.

258. Similarly, Jefferies & Company, Inc. reported on April 15, 2005:

> The takeaways from the Investor Day from our perspective are: 1) Connetics has an impressive pipeline, both in terms of breadth and the staging of various product candidates; 2) **Velac clinical data is solid, and the drug has the potential to become a major growth driver for Connetics;** 3) Evoclin's strong initial uptake reaffirms Connetics' expertise in launching new products, and increases our confidence in a strong commercial launch of Velac. While Evoclin and Velac are expected to drive strong growth (70%+) over the next couple of years, we believe Connetics' evolving pipeline holds the key to its long-term success.
>
> * * *
>
> Evoclin marked Connetics' entry into the acne market. Velac will extend that franchise.
>
> * * *
>
> **Velac addresses an unmet need among dermatologists**
>
> Velac combines two commonly prescribed treatments for acne, clindamycin (an antibiotic) and tretinoin (a retinoid). The two treatments are complementary to each other. Topical antimicrobial agents (like clindamycin) are effective in the treatment of inflammatory disease. Topical retinoids, on the other hand, are affective in both the treatment and prevention of the primary lesion of acne, the comedo (or non-inflammatory lesion), and thereby limit the formation of inflammatory lesions. Topical clindamycin is most effective when used in combination with benzoyl peroxide or topical retinoids. Randomized clinical trials have demonstrated a reduction in total lesion counts of 50-70% when combination therapy is used. Despite the established efficacy of the combination therapy, poor compliance with the regimen poses a challenge for dermatologists. The growth in BenzaClin and Duac aptly demonstrates the market potential for combination products. The high quality of the clinical data from the two pivotal Velac trials, comments from a practicing dermatologist who addressed the Investor Day, coupled with the thoughts expressed in an article in last week's issue of the New England Journal of Medicine (see footnote 1), leads us to the conclusion that Velac will be a commercial success.

259. Defendants' statements to analysts and investors at the Company's annual Analyst and Investor Day were materially false and misleading for the reasons set forth above in Section V.A. In particular, Defendants' statements to the market concerning the effectiveness of Velac as a treatment for acne, the size of the market for acne medication, and the likely revenues to be obtained in 2005 omitted the fact that Defendants had been told by the FDA, **just the day before**, that the Mouse Study results demonstrated Velac was a potential carcinogen and this was a

"serious" concern. As a result, Defendants knew Velac would not get approval by the PDUFA date and the FDA would – at the very least – require the Company to run additional testing to demonstrate that Velac was not a carcinogen and that this additional testing would push out approval by many months if not years.

260. On April 26, 2005, Connetics issued a press release entitled "Connetics Announces First Quarter Results with Product Sales up 79%" (the "April 26, 2005 Press Release"). The April 26, 2005 Press Release contained numerous false and misleading statements and omissions. The April 26, 2005 Press Release stated:

> Over the past several weeks Connetics has been responding to the Food and Drug Administration's ("FDA") questions regarding the Company's New Drug Application ("NDA") for its product candidate Velac. As part of this dialogue, the Company recently received communications from the FDA indicating that the agency was interpreting some of the results of a pre-clinical study for Velac® Gel differently than the Company did in the NDA submission. The preclinical study in question involved a transgenic mouse model. In the study, there was a positive response to the product. The Company carefully analyzed the results with a panel of leading toxicologists and experts in this model. The experts advised the Company that the transgenic mouse model is known to have limitations, and the experts concluded that the positive response was the result of a limitation of the model. The advice of these experts is supported by other products which had a positive finding but were ultimately approved based on additional work in other animal models. The Company is continuing its discussions with the FDA and expects to submit additional information which further supports the Company's original conclusion.

261. The April 26, 2005 Press Release also stated:

> For the second quarter of 2005, Connetics projects total revenue of $45 million to $47 million. Second quarter combined SG&A and R&D expenses are projected to be in the range of $34 million to $36 million. Earnings per diluted share for the second quarter of 2005 are projected to be $0.06 to $0.08.
>
> Reiterating 2005 financial guidance as updated on April 14, 2005, the Company anticipates total revenues to be in the range of $195 million to $206 million and combined SG&A and R&D expenses to be in the range of $121 million to $128 million. Earnings per diluted share for 2005 are expected to be $0.88 to $0.92. 2005 guidance assumes the launch of Velac in the third quarter.

262. Although partially disclosing certain issues related to Velac, these statements were materially false and misleading for the reasons set forth above in Section V.A. In particular, Defendants failed to disclose that the Company had been informed by an expert panel that the panel knew of no drug that exhibited a similar result and was approved by the FDA.

Defendants also failed to disclose, that the positive Mouse Test meant the FDA would – at the very least – require the Company to run additional testing to demonstrate that Velac was not a carcinogen and that this additional testing would push out approval by many months if not years. The Company also failed to disclose the specific information that the ECAC told Connetics that "this is a serious issue for a topical product for the treatment of acne." In addition, projecting large revenues for the product while concealing the results of the FDA-required laboratory study indicating that Velac was carcinogenic and that the Company had been informed by an expert panel that the panel knew of no drug that exhibited a similar result and was approved by the FDA was materially false and misleading.

263. On April 26, 2005, Connetics had a conference call with investors that was participated in by, among others, Defendants Wiggans, Higgins and Vontz (the "April 26, 2005 Conference Call"). Defendants made numerous false and misleading statements on the April 26, 2005 Conference Call, as set forth above. In addition to the statements set forth above, on the April 26, 2005 Conference Call Defendant Wiggans stated:

> Regarding Velac, we are – we continue to be in active discussions with FDA on their review of our NDA. As we've moved through the review process, we've been pleased with the review. And up to this point, we've been in active communication with the agency and have continued to be in active communication with the agency over the last several weeks, answering their questions as they finalize their review of the various sections.
>
> As part of this review, we recently received communications that indicated FDA were interpreting results of one of our pre-clinical studies in a different fashion than we did in our submission. I realize over the past several weeks there's been speculation regarding the approvability of a new retinoid, or approvability of a combo product. The question that they have asked is unrelated to either one of these subjects.
>
> We conducted one of our pre-clinical studies in a transgenic mouse model. And in that study, there was a positive response to our product. At the time, **we carefully analyzed the results with a panel of leading experts** in this model and leading toxicologists.
>
> The outcome of that was that **the experts advised us that this mouse model is known to have limitations** and they concluded that the positive response was a result of one of these limitations of the model.
>
> Their advice is supported in fact, by other products which have had a positive finding in this model, resulting in a clinical hold only to be released later based upon submission of additional data.

> And in fact, benzoyl peroxide, a commonly used OTC acne product, an ingredient in several prescription acne products, has Rx labeling that notes a positive result in this model.
>
> Because up to this point FDA had not raised this issue with us, we were surprised to received this information; however, we are in discussions with them on their question and we expect to submit additional information well before the PDUFA date, which further support our original conclusion included in the NDA.
> While I realize that this question might raise more questions, rather than answers for you, just as it did us, I can tell you that we are very committed to working with the FDA to get them the information so this issue can be resolved and enable us to launch Velac on schedule.

264. On the April 26, 2005 Conference Call, Defendant Higgins stated:

> For the second quarter, we're forecasting revenues of $45 to $47 million combined for total revenues. On expense of $34 to $36 million . . .
>
> With this revenue and expense guidance, we forecast EPS on a fully diluted basis to be in the range of $0.06 to $0.08 for the second quarter . . .
>
> **We are, of course, forecasting the launch of Velac in the third quarter at this time with this guidance.** And I do want to comment that we've enjoyed strong fourth quarter revenues the last several years. It seems to be a very significant quarter for dermatology products, and certainly we have included that in our assumptions.

265. Although partially disclosing certain issues related to Velac, these statements were materially false and misleading for the reasons set forth above in Section V.A. In particular, Defendants failed to disclose that the Company had been informed by an expert panel that the panel knew of no drug that exhibited a similar result and was approved by the FDA. The Company also failed to disclose the specific information that the ECAC told Connetics that "this is a serious issue for a topical product for the treatment of acne." Defendants also knew, but failed to disclose, the positive Mouse Test meant the FDA would – at the very least – require the Company to run additional testing to demonstrate that Velac was not a carcinogen and that this additional testing would push out approval by many months if not years. In addition, projecting large revenues for the product while concealing the results of the FDA-required laboratory study indicating that Velac was carcinogenic and that the Company had been informed by an expert panel that the panel knew of no drug that exhibited a similar result and was approved by the FDA was materially false and misleading.

266. After the April 26, 2005 analyst Conference Call, Defendants falsely claimed

"that only one mouse" in the Tg.AC study developed skin tumors. On April 27, 2005, Jeffries & Company, Inc. issued an analyst report written by David H. Windley, CFA, CPA, in which he described his meeting with Defendants as follows:

> Here is an excerpt from the FDA approved label for the acne treatment BenzaClin topical gel, a combination product consisting of clindamycin (one of Velac's ingredients) and benzoyl peroxide. The quote is taken from the section on Carcinogenesis, Mutagenesis, Impairment of Fertility on page 5 of the label.
>
> "Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. The clinical significance of this is unknown. Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment."
>
> In preclinical studies, Velac was tested in the same mice specimen as underlined above. **In our off-line conversation, management revealed that only one mouse displayed a similar response as the one mentioned in the quote above.** Management evaluated this data while Velac was under development and decided that the response does not have clinical relevance.

267. Moreover, as explained above (¶¶121-125), it was misleading for Defendants to compare Velac's development and the likelihood of Velac's approval by the PDUFA date with the FDA's approval of benzoyl peroxide based on the label for BenzaClin. In particular, the product insert provided with BenzaClin (prior to May 23, 2007) disclosing that it was approved by the FDA despite having tested positive in a Tg.AC mouse study does not disclose obvious critical facts necessary for drawing any legitimate comparison to Velac.

268. On or about May 10, 2005, Connetics filed with the SEC Connetics' Form 10-Q for the quarter ending March 31, 2005 (the "1Q05 10-Q"). The 1Q05 10-Q was signed and certified by Defendants Wiggans and Higgins consistent with the statements in ¶¶215-217.

269. The 1Q05 10-Q reported the following results for the three month period ended March 31, 2005:

(i) Product Revenues of $42,190,000;

(ii) Revenues of $42,371,000;

(iii) Income from operations of $1,499,000;

(iv) Net Income of $1,041,000;

(v) Basic Net Income per share of $0.03; and

(vi) Diluted Net Income per share of $ 0.03.

270. The 1Q05 10-Q also stated ". . . We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, when title has passed, the price is fixed or determinable, and we are reasonably assured of collecting the resulting receivable. We recognize product revenues net of estimated allowances for discounts, returns, rebates, and chargebacks."

271. These statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, Connetics admits in its Restatement that the financial statements for the first quarter 2005 were false when made. These statements reported artificially inflated revenues which were the result of the Company shipping excess product to distributors that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP.

272. On June 13, 2005, Connetics issued a press release entitled "Connetics Receives FDA Non-Approvable Letter For Velac" (the "June 13, 2005 Press Release"). The June 13, 2005 Press Release disclosed:

> . . . the U.S. Food and Drug Administration (FDA) issued a non-approvable letter dated June 10, 2005 for Velac® (a combination of 1% clindamycin and 0.025% tretinoin) Gel, an investigational new drug formulation for treating acne. The only issue raised in the non-approvable letter was a positive carcinogenicity signal that was detected in a TgAC mouse dermal carcinogenicity study.

273. The June 13, 2005 Press Release also stated:

> As a result of today's announcement, Connetics now projects 2005 total revenues to be $182 million to $188 million, down from previous guidance of $195 million to $206 million. Combined SG&A and R&D expenses for 2005 are projected to be between $121.5 million and $125.0 million. Diluted EPS for 2005 is projected to be in the range of $0.66 to $0.70, versus previous guidance of $0.88 to $0.92. The revised revenue and earnings guidance represents growth of approximately 28% over 2004 revenues and 33% over 2004 earnings.

274. These statements were materially false and misleading for the reasons set forth above in Section V.A (statements regarding Velac).

275. On August 2, 2005, Connetics hosted a conference call with investors that was participated in by, among others, Defendants Wiggans, Higgins and Vontz (the "August 2, 2005

Conference Call"). On the August 2, 2005 Conference Call, Defendant Wiggans stated:

> On the revenue side, we recorded $18.3 million in sales for Soriatane, we're very pleased with this. It is the highest level of net sales since we acquired the brand at the beginning of 2004. Evoclin, we reported $7 million, which includes sales to an international distributor of about $900,000. We're very pleased with this new channel. It was unexpected. We sold just about $50,000 to the same group in the first quarter. And we're pleased with this new channel. And we're pleased with their – their demand in ordering. Luxiq came in at $5.8 million, and OLUX net sales for the second quarter are $14 million. The total rollup when we look at combined product revenues, we have sales of $45.2 million, we're very pleased with this. It is a record high for the Company, and consistent with our prescription performance, suggests nice growth for the business.
>
> I – I do want to give some additional commentary around the returns, specifically relating to OLUX in the second quarter. We did see unusually high returns for OLUX and particularly for the 100-gram unit size. We have two units, and the OLUX 100-gram size in particular. Given the returns that were – were reported during the quarter, as well as an estimate for future potential liability, we have booked a $2.3 million provision this period, then return activity we experienced was unexpected, and it relates to the actual returned, and information that we received in the second quarter. **We did do a very thorough review of OLUX, as well as all of our products and we concluded that the returns are due to the distribution ordering practice of investment purchasing, or forwarding buying of product in anticipation of price increases, namely by our two largest wholesalers back in 2004**.
>
> As most of you know, at the end of 2004 we did enter distribution service agreements, or DSA's, as they're called, with both of these wholesalers. The DSA's, among other things, **they do prohibit investment purchasing and they also make available to us considerably more information about the inventory levels and channel distribution by the wholesalers**. I do want to clarify the product that has been returned, or is expected to be returned was purchased prior to Connetics entering these agreements. **We do believe the high second quarter return provision relating to investment purchasing is a one-time event. We also believe we've taken the appropriate reserves, we have more information available to us now under these agreements and will be monitoring the shelf life of existing product as it moves through the distribution channel going forward**.

276. On the August 2, 2005 Conference Call, Defendant Higgins had the following exchange with an analyst:

> **Analyst:** . . . And what were inventory levels for all products at the end of the quarter? How does that compare to last quarter? And then, specifically, on Soriatane and Evoclin, obviously those numbers came in pretty strong. Was there any stocking there, or does that truly reflect that prescription demand for those products?
>
> **Higgins:** . . . **we're spending more time matching shipments to demand**, that's one of our objectives, I think with regard to your previous question, the levels of inventory at the end of this quarter, versus last quarter [are] fundamentally unchanged.

277. These statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, these statements were misleading because the Company shipped excess product to distributors that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP. In addition, as corroborated by numerous former employees contacted by Lead Plaintiff, the internal forecasts were manipulated and "changed on a whim" with disregard to inventory levels in order to meet Wall Street numbers.

278. On November 1, 2005, Connetics issued a press release entitled "Connetics Reports Third Quarter Revenues of $55.3 Million and Diluted EPS of $0.39" (the "November 1, 2005 Press Release"). The November 1, 2005 Press Release stated:

> Total revenues for the third quarter of 2005 were $55.3 million, an increase of 48% over total revenues of $37.3 million in the third quarter of 2004. Total product revenues for the quarter increased 49% to $55.2 million, up from $37.0 million in the third quarter of 2004, reflecting contribution from sales of Evoclin™, which was launched in December 2004, and continued growth in sales of Soriatane®, OLUX® and Luxíq®. Third quarter product sales included: Soriatane $23.1 million, Evoclin $7.7 million, OLUX $17.3 million and Luxíq $7.0 million.

279. The November 1, 2005 Press Release also stated:

> For the nine months ended September 30, 2005, total revenues were $143.1 million, an increase of 42% compared with total revenues of $100.6 million for the first nine months of 2004.
>
> SG&A expenses for the first nine months of 2005 were $76.1 million compared with $49.1 million for the first nine months of 2004. R&D expenses for the first nine months of 2005 were $22.8 million, up from $15.3 million in the first nine months of 2004.
>
> Net income was $18.9 million, or $0.50 per diluted share, compared with net income of $13.0 million, or $0.35 per diluted share, for the comparable period last year.
>
> For the fourth quarter of 2005 Connetics projects total revenues of $47 million to $49 million, and combined SG&A and R&D expenses in the range of $29 million to $30 million. Earnings per share on a diluted "If Converted" basis for the fourth quarter of 2005 are projected to be $0.24 to $0.26.
>
> The Company's full year total revenues are expected to be $190 million to $192 million, compared with prior guidance of $185 million to $190 million. Combined SG&A and R&D expenses are now projected to be in the range of $128 million to $129 million, compared with prior guidance of $125 million to $127 million. Earnings per share on a diluted "If Converted" basis for

> 2005 are expected to be $0.74 to $0.76, compared with prior guidance of $0.66 to $0.70.

280. The November 1, 2005 Press Release quoted Defendant Wiggans as stating:

> The third quarter marked another solid period of commercial growth while we continued to make progress advancing our product pipeline . . . our product portfolio continues to enjoy revenue growth. We are investing significantly in our pipeline to drive our future growth, and we have several global licenses that we expect will begin generating new royalty and contract revenues for the Company in the coming year. In the final months of 2005, we continue to build a broad platform that will allow Connetics to become the leading medical dermatology company in the U.S.

281. These statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, these statements reported artificially inflated revenues which Defendants knew were the result of the Company shipping excess product to distributors that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP.

282. On or about November 9, 2005, Connetics filed with the SEC Connetics' Form 10-Q for the quarter ending September 30, 2005 (the "3Q05 10-Q"). The 3Q05 10-Q was signed and certified by Defendants Wiggans and Higgins in a manner identical, or nearly identical, to the statements made in ¶¶215-217.

283. The 3Q05 10-Q reported the following results for the three month period ended September 30, 2005:

(i) Product Revenues of $55,183,000;

(ii) Revenues of $55,341,000;

(iii) Income from operations of $15,675,000;

(iv) Net Income of $15,365,000;

(v) Basic Net Income per share of $0.44; and

(vi) Diluted Net Income per share of $ 0.39.

284. The 3Q05 10-Q also stated ". . . We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, when title has passed, the price is fixed or determinable, and we are reasonably assured of collecting the resulting receivable. We recognize

product revenues net of estimated allowances for discounts, returns, rebates, and chargebacks."

285. These statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, Connetics admits in its Restatement that the financial statements for third quarter 2005 were false when made. These statements reported artificially inflated revenues which Defendants knew were the result of the Company shipping excess product to distributors that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP.

286. On December 19, 2005, Connetics hosted a conference call with investors that was participated in by, among others, Defendants Wiggans, Higgins and Vontz (the "December 19, 2005 Conference Call"). On the December 19, 2005 Conference Call, Defendant Higgins said:

> For 2006, as we indicated in the press release, we're forecasting revenues of $215 to $218 million in total revenues. This represents a 17% growth over 2005 revenues. All four current products are expected to enjoy revenue growth with Evoclin, just in its second year, growing the most . . .
>
> When we look at EPS, EPS is projected to be $0.86 to $0.88 on a diluted if-converted basis. This does exclude the impact of FAS 123, or the expenses associated with stock-based compensation. We estimate that FAS 123 will have an impact to net income in '06 of approximately $6 to $7 million, or $0.09 to $0.11 dilution to earnings per share . . .
>
> Just a comment about our profitability. We're pleased with our outlook for '06. When we look at the 2006 profitability, it represents approximately 45% growth over 2005, excluding the one-time tax benefit. And earlier, we had indicated we expected our 2006 tax rate to be in the mid-20% range. That had been our plan in case. We had given some general guidance. And assuming a 25% tax rate, our '06 earnings per share would have actually been $1.05 per share.

287. On the December 19, 2005 Conference Call, Defendant Wiggans had the following exchange with an analyst:

> **Analyst:** Okay. And, then, maybe just following up on that, could you just kind of give us a sense, then, sort of where you expect to be at year end in terms of wholesaler inventory levels on the range of products in the portfolio?
>
> **Wiggans** Well, we've always – I mean, we track, now, shipments to demand. We have for some period of time. And so we, again, **we don't see any fundamental changes in our inventory levels.** We haven't adjusted any

> of the others. Soriatane is really the bulk of the change. We've previously said 8 to 12 weeks is our range. Soriatane was at the high end of that. We expect to get it to the low end of that.

288. These statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, these statements reported artificially inflated revenues which Defendants knew were the result of the Company shipping excess product to distributors that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP. In addition, according to CW4, Connetics regularly placed four months of inventory into the channel, not the 12 weeks to 8 weeks falsely stated by Defendants in this conference call. Indeed, Connetics' admits in its Restatement that inventory levels exceeded four months.

289. On January 31, 2006, Connetics issued a press release entitled "Connetics Reports Fourth Quarter Revenues of $41.3 Million and EPS of $0.40" (the "January 31, 2006 Press Release"). The January 31, 2006 Press Release stated:

> Connetics . . . today reported net income for the quarter ended December 31, 2005 of $15.1 million, or $0.40 earnings per share on a diluted "If-Converted" basis. This compares with net income of $6.0 million, or $0.16 earnings per share on a diluted basis, for the comparable quarter in 2004. The results in the 2005 fourth quarter include a positive impact of $0.25 per diluted share from recording a tax asset of $9.9 million, as previously announced.
>
> Total revenues for the fourth quarter of 2005 were $41.3 million, compared with total revenues of $43.8 million in the fourth quarter of 2004. Fourth quarter 2005 product revenues included OLUX(R) sales of $14.7 million, Soriatane(R) sales of $13.6 million, Evoclin(TM) sales of $6.9 million and Luxiq(R) sales of $5.6 million.

290. The January 31, 2006 Press Release also stated:

> Net income for 2005 was $34.1 million, or $0.89 per diluted "If-Converted" share, compared with net income of $19.0 million, or $0.51 per diluted share, in 2004. Full year 2005 results include a positive impact of $0.24 per diluted share from recording a tax asset of $9.9 million during the fourth quarter.
>
> Total revenues for 2005 rose 28% to $184.4 million, and product revenues increased 29% to $183.4 million, reflecting growth in OLUX and Luxíq, and a full year revenue contribution of Soriatane and Evoclin. SG&A expenses increased to $97.4 million for 2005, compared with $73.2 million for 2004, primarily due to costs associated with a larger sales force, promotional activities for Evoclin and increased headcount. Due to increased formulation

> and clinical development activities, R&D expenses for 2005 increased to $31.9 million, compared with R&D expenses of $21.5 million in 2004.

291. The January 31, 2006 Press Release quoted Defendant Wiggans as stating:

> Evoclin reached record market share levels during the quarter, and our other brands remain solid performers in increasingly competitive markets and against new entrants . . . . We are delighted that two of our partners, Pfizer and Novartis, recently received approvals to market products that incorporate Connetics' patented topical delivery technologies. With the breadth of our commercial portfolio, the expected introduction of Desilux in the fourth quarter of this year, and our expanded sales presence, we believe Connetics is positioned for continued growth in 2006.

292. These statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, Connetics admits in its Restatement that the financial statements for the fourth quarter 2005 were false when made. These statements were misleading because Defendants knew the artificially inflated sales were the result of the Company shipping excess product to distributors that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP. In addition, according to CW9, the internal forecasts were manipulated and "changed on a whim" with disregard to inventory levels in order to meet Wall Street numbers.

293. On March 13, 2006, Connetics filed its annual report on Form 10-K for the year ended December 31, 2005 (the "2005 10-K"), wherein the Company reaffirmed its previously announced financial results and reported net income of $33,958,000 for 2005. The Company's 2005 10-K was signed by Defendants Wiggans and Higgins. The 2005 10-K was signed and certified by Defendants Wiggans and Higgins in a manner identical, or nearly identical, to the statements made in ¶¶215-216.

294. The 2005 10-K also stated ". . . We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, when title has passed, the price is fixed or determinable, and we are reasonably assured of collecting the resulting receivable. We recognize product revenues net of estimated allowances for discounts, returns, rebates, and chargebacks."

295. The 2005 10-K reported the following results for the fiscal year ended December 31, 2005:

(i) Product Revenues of $183,312,000;

(ii) Revenues of $184,264,000;

(iii) Income from operations of $23,897,000;

(iv) Net Income of $33,958,000;

(v) Basic Net income per share of $0.97; and

(vi) Diluted Net Income per share of $ 0.89.

296. The 2005 10-K also stated:

> In the second quarter of 2005, our wholesaler customers returned an unexpectedly high amount of expiring and expired OLUX Foam. These return levels were significantly above historical levels. Based on our analysis, we recorded a charge to product revenues of $2.3 million in the second quarter for expired and estimated expiring products at our customers associated with product sales recorded in prior periods.

297. These statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, Connetics admits in its Restatement that the financial statements for year ended December 31, 2005 were false when made. These statements were misleading because Defendants knew the artificially inflated sales were the result of the Company shipping excess product to distributors that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP. In addition, as corroborated by numerous former employees contacted by Lead Plaintiff, the internal forecasts were manipulated and "changed on a whim" with disregard to inventory levels in order to meet Wall Street numbers.

298. On May 3, 2006, after the market closed, Connetics issued a press release entitled "Results of Operations and Financial Condition" (the "May 3, 2006 Press Release"). The May 3, 2006 Press Release stated:

> On May 3, 2006, the Company concluded that its financial statements for the year ended December 31, 2005, and potentially additional periods, should no longer be relied upon. The Company has determined that its rebate reserves as of the end of 2005 were understated. Rebates are contractual discounts offered to government programs and private health plans which are eligible for rebates at the time prescriptions are dispensed, subject to various conditions. The Company records quarterly reserve provisions for rebates by estimating rebate liability for product sold, based on factors such as timing and terms of plans under contract, time to process rebates, product pricing,

> sales volumes, units held by distributors, and prescription trends. Upon review, the Company has concluded that the rebate rates and method used to calculate the rebate liability did not fully capture the impact of these factors in its historical provision. Accordingly, the Company plans to restate its financial statements for the year ended December 31, 2005, and potentially additional periods.

299. The May 3, 2006 Press Release also stated:

> On a preliminary basis, net income for the first quarter ended March 31, 2006 was $0.8 million, or $0.02 earnings per share on a diluted basis, including stock-based compensation expense of $1.6 million, or $0.05 per diluted share, reflecting the adoption of SFAS 123R, accounting for stock-based compensation, as of January 1, 2006. On a non-GAAP basis excluding stock-based compensation, net income for the first quarter of 2006 was $2.4 million, or $0.07 per diluted share . . .
>
> For the second quarter of 2006, Connetics projects total revenues of $50.5 million to $52.5 million. Second quarter operating expenses, including depreciation, are projected to be in the range of $37 million to $38 million. Connetics projects earnings per share on a diluted basis for the second quarter of 2006 of $0.07 to $0.09, including an estimated $1.6 million or approximately $0.04 per diluted share impact from expensing stock-based compensation. Non-GAAP diluted EPS for the second quarter of 2006 excluding expense for stock-based compensation is projected to be in the range of $0.11 to $0.13.
>
> Based on information currently available to the Company, Connetics is lowering 2006 revenue guidance. Total revenues are now expected to be $211 million to $217 million, compared with prior guidance of $221 million to $225 million, reflecting increased competition in the psoriasis market.

300. Although partially disclosing certain issues related to Connetics' financial statements, these statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, these statements were misleading because Defendants knew the artificially inflated sales were the result of the Company shipping excess product to distributors that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP.

301. On May 3, 2006 Connetics hosted a conference call with investors that was participated in by, among others, Defendants Wiggans, Higgins and Vontz (the "May 3, 2006 Conference Call"). On the May 3, 2006 Conference Call, Defendant Wiggans stated:

> For the first quarter, we recorded product revenues of $47.7 million and earnings per share, excluding stock option expensing, of $0.07. As we discussed in our press release, we've determined that we should begin accounting for rebates to managed care plans and our government programs

> differently. Since we began selling our first product, Luxiq, in 1999 we've taken quarterly reserves to account for rebate obligation. However, as Connetics' business has grown and our contracts have grown, so has our reserve liability.
>
> After a careful review of our reserve levels we have concluded that our product rebates are under-reserved for future liabilities. This is a historical adjustment to be allocated over the past several years and these adjustments will have no impact on revenues going forward . . .
>
> Although as I mentioned before, in March we hit all-time highs for OLUX, the prescription trends for OLUX and Soriatane are below our forecast levels. Given this run rate, we now believe we will not be able to achieve our original forecasts. As a result, we are reducing our revenue guidance for the year from $221 to $225 million, to $211 to $217 million . . .
>
> * * *
>
> The rebate accounting issue has no effect whatsoever on future trends. And to the degree that we may do destocking over time, that was built into the original guidance. So of the three points you made, Mark, the reason for the guidance change is the way we see the prescriptions. As you can – as you may recall last year, we had a pretty big second half forecast. And a lot of the calls – or a lot of the questions on the first quarter call were; Can you really grow the business that much in the second half of the year? Last year we were able to do that. Our assessment right now is we won't be able to do that in the second half of the year unless we bend the trend.

302. On the May 3, 2006 Conference Call, Defendant Vontz stated: "Any destocking activities over the coming quarters have been accounted for in our revised guidance given today."

303. On the May 3, 2006 Conference Call, Defendant Higgins stated:

> As [Defendant Wiggans] alluded to, the total revenue guidance is now $211 to $217 million, approximately. This is approximately 4% lower than our original guidance. And the reduction when you look at it on a product basis is driven more by lower revenue expectations for OLUX and Soriatane. The guidance includes revenue from the anticipated fourth quarter launch of Desilux, as well as royalty and contract revenue. When we look at the full year gross margins, we believe for the full year we'll be slightly higher than our beginning of the year forecast at about 91%. Operating expenses, excluding stock-based comp, are unchanged at $146 to $148 million.
>
> Finally, let me provide some comments about our rebate accounting. To start with, rebates are – background, rebates are contractual discounts offered to governmental entities, such as state Medicaid programs and private health plans. The entities under contract are eligible for rebates at the time prescriptions are dispensed. Of course, there are various conditions. They have to, in certain cases, have national market share levels, et cetera. The Company has literally taken estimate reserves for rebates against quarterly sales. I'll add that the calculation is complex. It's based on a multiple of factors, including the timing and the terms of the rebate contracts, the time to process the rebate, product pricing, look at quarterly sales volume, unit sales to distributors, as well as prescription trends.
>
> Upon review, the Company concluded the rebate rates and the method used to calculate the rebate liability in prior periods did not fully capture the

> impact of all of these factors. And that our reserve for the future liability is low. We estimate that the cumulative impact of the change as of the end of 2005 is approximately $8 to $9 million.

304. On the May 3, 2006 Conference Call, Defendants Wiggans, Higgins and Vontz had the following exchange with an analyst:

> **Analyst:** I just wanted to clarify, in understanding this issue what precipitated the recognition that you were under-reserved? Was there a threat of a whistle blower lawsuit with the regard to under-reserving or exactly what was it that drew this out now as opposed to let's say at the year-end process when the K was completed?
>
> **Wiggans:** . . . We want to make it very clear that this issue arose in our examination of our reserves and in consultation with Ernst & Young. It was something we identified. We thought it might be a longer project. But I think as we got into it and understood the amounts and consulted with E&Y, the time to do it was now. And I think you can count on us, whenever we identify an issue like this we address it. Something that we wish hadn't arisen but it has and we will fix it and we'll get it behind us. **And it arose during the first quarter**.
>
> **Vontz**: Let me answer this. I don't want to oversimplify it Ken. But I think the short answer is, the business is a lot more complicated now than it was a couple of years ago. This is a function of growth, it's a function of contracting. As an example, when we bought Soriatane there were very few contracts. We have contracted much more aggressively. So the – all of these things, and again, I don't want to oversimplify this, and I'm not going to dodge the question. All these things are unrelated and they're a function of growing the business. The Soriatane reversal in the third quarter was really a reversal of a reserve that we had taken very conservatively and in conjunction with our auditors when we acquired the product. And when the actuals came in back from Roche we had over-reserved. So a series of accounting issues but they are unrelated.
>
> **Higgins:** . . . just a little more color. The third quarter adjustment was a change in estimates related specifically to the acquisition accounting at the time we acquired Soriatane in early '04. Actually, we were looking at existing data at that time, we made various assumptions in terms of what the reserve rates should be for that product. And really late into '05, we had been seeking new or additional data from Roche. It was, I think, late in the third quarter that we finally got data sufficient to justify we were over-reserved. And that was the release of that particular item, again specifically relating to the acquisition accounting. The topic we're looking at here really is I'll say a historical or legacy issue that really goes back over time. We have four products, we launched Soriatane, we launched Evoclin, we've got increased rebate contracting. The process for us now is to carefully evaluate in which periods we need to increase the reserve. As [Defendant Wiggans] alluded to in his opening remarks, this will be an adjustment to our '05 ending year and balance. **Of course, it won't impact our business going forward** . . .

305. On the May 3, 2006 Conference Call, Defendant Wiggans had the following exchange with another analyst:

Analyst: Okay. And then just in terms of the inventory levels, as you got more clarity, did you say – did you notice that inventories had risen over the course of the past quarter, or that they were just staying steady at a level higher than you had expected?

Wiggans: . . . as we've said in the past, one thing we have – one thing I believe we've gotten better at over the last several quarters, or year or so, is really tracking shipments to prescription demand. That is something we've had a pretty good handle on, the actual amounts in the channel, less visibility. I think over the last quarter actually, the inventory levels in the channel based on the reports we're getting now, were very slightly lower. So they went down slightly, probably not a significant amount. But I think what we've been able to do for some time is track shipments versus demand. I don't think we had the degree of clarity on the amount in the channel that we do now, or think we do now.

Analyst: So just you're raising the number based on increased clarity, not an actual --?

Wiggans: Correct. That is correct . . .

306. Defendants Wiggans, Higgins and Vontz also had the following exchange with an analyst:

Analyst: And a follow-up on the rebate issue. I was a little confused as to why you wouldn't have seen this issue earlier than this reporting period?

Higgins: . . . the rebate calculation is very complex and based on multiple factors. We are using the rate and method historically that we thought was providing sufficient reserve. And again, it was in the quarter close process, very recently, that we got a sense, looking at--wholesaler channel, the effective recent price increases, recent rebate contracting, again, just a number of factors. As well as looking into industry practices, that we concluded that we were under-reserved.

Vontz: . . . one other to share with you is we also have to forecast not only what rebate is being paid to each contract situation but what portion of the business will flow through that on any given quarter. So, it gets to be a very complex forecasting methodology.

Wiggans: Let me just add one last thing. And we said this at the outset. We have been doing it this way for six years. And I think it was a good thing for our finance group to all of a sudden say: "here's another area we ought to look at." But in terms of why we didn't notice it sooner, we've been doing it the same way for six years. It seemed like the right way to do it. Everything always checked out when we got the invoices and we paid the amount. And adjustments might need to be made from quarter to quarter, but were immaterial, so that's really the reason we didn't catch it before.

307. Although partially disclosing certain issues related to Connetics' financial statements, these statements were materially false and misleading for the reasons set forth above in Section V.B. In particular, these statements were misleading because Defendants knew the artificially inflated sales were the result of the Company shipping excess product to distributors

that exceeded product demand in the retail channel. Connetics' intentional channel-stuffing also caused Connetics' accruals for rebates, chargebacks and returns to be materially understated which materially overstated the Company's earnings in violation of GAAP. In addition, as corroborated by numerous former employees contacted by Lead Plaintiff, the internal forecasts were manipulated and "changed on a whim" with disregard to inventory levels in order to meet Wall Street numbers.

VII. ADDITIONAL ALLEGATIONS OF SCIENTER

308. The Insider Defendants and Connetics each acted with scienter with respect to the materially false and misleading statements discussed herein, in that they had actual knowledge that the statements were false or misleading, or acted with reckless disregard for the truth or falsity of those statements. Defendants Yaroshinsky and Zak each acted with scienter with respect to their illegal trading in Connectics securities. In addition to the allegations set forth above, Defendants' scienter is established by the following facts.

A. Evidence Of Intentional Or Reckless Misconduct

309. Defendants Wiggans, Higgins, Vontz, Krochmal and Yaroshinsky had actual knowledge of the issues with the safety and approvability of Velac. According to CW3, Defendants Yaroshinsky, Vontz and Krochmal were directly in charge of overseeing the pre-clinical testing of Velac and were involved in every step of the developmental process for the drug, including overseeing the Mouse Study. Throughout the Class Period, Yaroshinsky reported directly to Vontz and Krochmal and provided regular updates on the Velac regulatory process and the progress of pre-clinical tests to Defendants Wiggans and Higgins. In particular, each of these Defendants had actual knowledge of the carcinogenic results of the Mouse Study and the June 28, 2004 comments from Connetics' panel of expert toxicologists. Indeed, according to CW3, "there was not a thing that went on in that organization that they [Wiggans, Higgins and Vontz] were not aware of." According to CW3, Defendant Vontz was "very hands-on" and closely monitored the Velac pre-clinical trials.

310. Further, Defendant Yaroshinsky was on the April 13, 2005 conference call where the FDA informed Connetics of its significant concerns about the safety of Velac (which

reiterated the concerns of Connetics' own toxicology experts and was based on the results of the Mouse Study, both of which each of the Officer Defendants already knew) and Defendant Yaroshinsky and others immediately informed Defendants Wiggans, Higgins, Vontz and Krochmal of this call. According to the SEC Complaint and admitted to by Defendant Yaroshinsky, Connetics immediately put in place a trading ban to prevent individuals with inside knowledge about the FDA call from conducting transactions in Connetics' securities. This trading ban could only have been put in place with the knowledge and approval of Defendants Wiggans, Higgins and Vontz.

311. Defendant Yaroshinsky's actual knowledge of the issues with the safety and approvability of Velac is further demonstrated by the following additional facts set forth in the SEC Complaint, as corroborated by Yaroshinsky's answer to the SEC complaint and by confidential witnesses, including CW4, who worked with Defendant Yaroshinsky:

(i) "Yaroshinsky's duties and responsibilities as Connetics' Vice President of Biostatistics and Clinical Operations included designing drug development studies, conducting the studies, analyzing the results and ultimately generating reports to the FDA for use in drug applications. In order to carry out his duties, Yaroshinsky was entrusted with, and had ready access to, non-public information concerning the approval process of Connetics' developmental stage drugs." (SEC Complaint ¶13.).

(ii) Yaroshinsky's insider trading activities as detailed herein, and admitted by Yaroshinsky in answering the SEC complaint.

(iii) "Defendant Yaroshinsky learned material, non-public information concerning the status of Velac Gel. He further knew, should have known, or was reckless in not knowing, that the information concerning the FDA's view of the carcinogenicity study was material and nonpublic." (*Id*. at ¶37.)

(iv) "Defendant Yaroshinsky communicated the material, non-public information concerning the FDA's comments and conclusions concerning the Velac Gel carcinogenicity study to Zak, for his direct or indirect personal benefit." (*Id*. at ¶39.)

312. The scienter of Defendants Wiggans, Higgins, Vontz and Krochmal regarding the issues with Velac is further demonstrated by the fact that Velac was the single most important product for the future of the Company. Throughout the Class Period, analysts estimated that the drug would account for up to $18.5 million in sales for fiscal year 2005, as high as $62 million

for fiscal year 2006, and approximately $90 million for fiscal year 2007. For fiscal year 2005, these sales figures would have represented – for this **single product** – a 13% increase in the Company's total sales for **all products** (as compared to fiscal year 2004), a 50% increase for fiscal year 2006, and a staggering **72%** increase for fiscal year 2007. Indeed, analysts regularly estimated that Velac would be the Company's largest selling product by fiscal year 2007. (*See e.g.*, 10/15/04 CIBC Report at 3.)

313. Moreover, Defendants Wiggans, Higgins, Vontz and Krochmal repeatedly made statements to the market demonstrating that they were focused on the development of Velac and were keeping themselves apprised of the Velac regulatory and testing processes. These statements demonstrate that each of these Defendants knew or should have known of all important developments relating to Velac.

314. Thus, Defendants Wiggans, Higgins, Vontz and Krochmal – the most senior executive officers of Connetics – actively monitored the status of this important drug throughout the Class Period, and each of them knew the safety and approvability issues with Velac that are discussed herein.

315. The scienter of Defendants Wiggans, Higgins and Vontz regarding both the issues with Velac and the financial statement fraud during the Class Period is also demonstrated by the membership of each of these Defendants on Connetics' Management Executive Committee. Connetics disclosed that the Management Executive Committee was responsible for "the overall direction, strategy and operations of Connetics, including, among other things, **corporate financial performance, commercial performance, research, development and product operations performance**." (2006 Schedule 14A Proxy at 11.) As high-level executives of Connetics and members of the Management Executive Committee, each of these Defendants had access to material non-public information not available to the public, including material non-public information regarding the regulatory approval process for Velac and the fraudulent channel-stuffing practices alleged herein. Indeed, as alleged in detail above, Lead Plaintiff's investigation has revealed substantial evidence that the Management Executive Committee played significant roles in the Velac approval process and in reviewing the Company's internal forecast

reports that were used to effect the fraudulent channel-stuffing practices.

316. Additional direct evidence of Defendants Wiggans, Higgins and Vontz's actual knowledge of and involvement in the fraudulent channel-stuffing practices described herein is set forth above in Section V.B.

B. The Insider Defendants And Connetics Raised $200 Million In A Private Bond Offering And Used The Proceeds For A Share Repurchase

317. On or about March 23, 2005, while Defendants were actively concealing the significant issues with the safety and approvability of Velac and causing the Company to issue materially false and misleading financial statements in violation of GAAP, Connetics issued $200 million principal amount of convertible senior notes maturing on March 30, 2015 (defined above as the "Bonds") pursuant to Rule 144A of the Securities Act (defined above as the "Private Placement").

318. The Private Placement was a highly unusual transaction for Connetics. For instance, the next largest such transaction that Connetics had conducted was a small issuance of $90 million of convertible notes in May 2003. After expenses of $7 million, Connetics received proceeds of nearly $193 million from the Private Placement.

319. The Insider Defendants were motivated to conceal the true state of the Company's finances and the issues with Velac so that the Company could conduct the lucrative Private Placement. If the true facts about the Company had been known, the Company could not have conducted the Private Placement. Indeed, as set forth below, in the first quarter of 2005 – while the Company reported profitability and earnings per share of 3 cents – the Company had actually suffered a **loss of 3 cents per share**. Had the market known the true state of the Company's finances immediately prior to the Private Placement, investors would not have purchased the Bonds, or paid anywhere near the price they did.

320. The Insider Defendants also received a highly unusual and concrete benefit from the completion of the Private Placement in the form of a share repurchase program that Connetics funded with a portion of the proceeds it received in the Private Placement. Specifically, the Insider Defendants caused Connetics to use $35 million of the proceeds to

repurchase 1,332,300 shares of Connetics' common stock at an average price of $26.27. By reducing the amount of Connetics' common stock in the public float using the proceeds of the Private Placement, the Insider Defendants were able to leverage their false statements to the market to immediately inflate the value of their own stock holdings – at no cost to themselves.

C. The Insider Defendants And Connetics Were Motivated To Meet Or Exceed Analyst Expectations

321. Throughout the Class Period, Connetics was preoccupied with meeting or exceeding the estimates that Wall Street analysts published for the company's quarterly and year-end growth and earnings. This obsession with meeting the "Wall Street numbers" is well-documented by the former Connetics employees contacted during Lead Plaintiffs' investigation and discussed above, including CW3, CW11, and CW7. Indeed, as detailed herein, there was a consistent effort to manipulate Connetics' forecasting process to justify "selling" enough inventory into the channel to meet Wall Street's expectations for Connetics' sales and revenues.

322. Connetics was covered by a number of securities analysts during the Class Period, and each of these analysts regularly reported on the Company's financial results and the major events impacting the Company. These analysts would formulate an assessment of the Company's financial position and future potential based on its reported results and information provided to Wall Street by Connetics' senior management. These assessments were reflected in the analysts' projected earnings for future fiscal periods, and published in their analysts' reports.

323. During the Class Period, the Company regularly met or exceeded analysts' estimates for its financial performance. However, as has now been admitted in the Restatement, had Connetics' financial statements been accurately reported, the Company regularly would have **missed** Wall Street's estimates during the Class Period. Indeed, as alleged in detail above, Connetics was only able to consistently meet and exceed Wall Street's estimates by using the accounting gimmickry specified herein. But for these fraudulent practices, the Company would have fallen short of Wall Street's estimates for most financial periods during the Class Period. The following chart shows Connetics' reported earnings per share ("EPS") as compared to its restated EPS for each quarter during the Class Period.

Connetics' Reported EPS v. Restated EPS During the Class Period		
Period	**Reported EPS**	**Restated EPS**
1Q04	$0.05	$0.04
2Q04	$0.19	$0.21
3Q04	$0.10	$0.09
4Q04	$0.17	$0.13
FY 2004	$0.51	$0.47
1Q05	$0.03	($0.03)
2Q05	$0.07	$0.07
3Q05	$0.39	$0.29
4Q05	$0.40	$0.36
FY 2005	$0.89	$0.70

324. As demonstrated by the positive analyst reaction to Connectics' reported EPS, these manipulations allowed the Company to project the illusion of success, which artificially inflated the price of the Company's publicly traded securities:

(i) On January 25, 2005, Connetics reported fourth quarter 2005 EPS of 17 cents per share, which beat analyst expectations by 1 cent. Analysts reacted favorably to this announcement. (*See* 1/26/05 Buckingham Report at 1 ("Connetics finished its first year of profitability with 2004 EPS of $0.52, **including 4Q04 EPS that topped our estimate and consensus by $0.01.**") In reality, however, if Connetics had accurately reported its financial results for that quarter, the market would have known that the Company actually earned 14 cents per share, or **2 cents per share below Wall Street expectations**.)

(ii) On April 26, 2005, Connetics reported first quarter 2005 EPS of 3 cents per share, which beat analyst expectations by 1 cent. Analysts reacted favorably to this announcement. (*See* 4/27/05 RBC Report at 1 ("Connetics reported 1Q05 EPS of $0.03 . . . this **beat our and consensus estimates of $0.02.**") In reality, however, if Connetics had accurately reported its financial results for that quarter, the market would have known that the Company actually **suffered a 3 cents per share loss for that quarter.**

(iii) On November 1, 2005, Connetics reported third quarter 2005 EPS of 39 cents per share, which was $0.02 less than consensus analyst expectations,. (*See* 11/2/05 Jefferies Report at 1.) In reality, however, if Connetics had accurately reported its financial results for that quarter, the market would have known that the Company actually earned 29 cents per share, **10 cents per share below Wall Street expectations.**

(iv) On January 31, 2006, Connetics reported fourth quarter 2005 EPS of 40 cents per share, which exceeded expectations by 1 cent. (*See* 2/1/06 FBR Report at 1 ("Connetics reported adjusted 4Q EPS last night a penny above our forecast and the consensus estimate.") In reality, however, if Connetics had accurately reported its financial results for that quarter, the market would have known that the Company actually earned 46 cents per share, **3 cents below Wall Street expectations**.

325. Connetics would not have made analyst forecasted earnings in 3Q05 had they not manipulated the Company's financial results in violation of GAAP. According to an analyst report issued by Jefferies & Company, Inc. issued on November 2, 2005, "CNCT reported 3Q05 EPS of $0.39, including a $0.16 reserve reversal benefit and $0.03 from a lower tax rate." Analysts, however, do not include such one-time gains as the reserve reversal and tax benefit when assessing a company's earnings per share. The Jefferies & Company report further stated: "Stripping out the reserve reversal and the tax benefit, EPS would have missed our estimate by at least a penny and consensus by $0.02." In truth, the Company had improperly recognized $0.10 EPS that was subsequently restated. Accordingly, had the Defendants not manipulated the numbers in 3Q05, the Company would have missed analysts' consensus EPS estimates by $0.12 – not just $0.02.

326. Similarly, Connetics would not have made analyst forecasted earnings in 1Q04 (or been on the low end of expectations) had they not manipulated the Company's financial results in violation of GAAP. The Company reported 1Q04 EPS of $0.05, which included $0.02 per share for a new accounting treatment for certain manufacturing and quality control expenses. Stripping out this one-time change to the accounting treatment, the Company's 1Q04 EPS was in line with analysts' estimates of $0.03 per share. However, after the Company was forced to restate its results, its EPS was only $0.04 per share. Stripping out the $0.02 per share benefit of the accounting change, the Company would have missed analysts' expectations.

327. As discussed above, there was constant pressure at Connetics – applied by Defendants Wiggans, Higgins and Vontz – to meet "Wall Street's numbers." Rather than meet these numbers through legitimate product launches and proper GAAP accounting, the Insider Defendants and Connetics used accounting gimmickry and fraudulently stuffed

inventory into the Company's distribution channels in an effort to artificially inflate the Company's reported results.

D. Insider Sales

328. During the Class Period, Defendants Wiggans, Higgins and Vontz collectively sold Connetics common stock generating sale proceeds in excess of $8,000,000, and therefore profited from the artificial inflation in Connetics stock. Defendants' sales in the 895 day period prior to the Class Period and during the Class Period are set forth in the tables below:

Filer	Trans. Date	Shares		Price	Total		Holdings	
VONTZ	07/29/02	25,000		10.405	260,125		17,682	
VONTZ	09/10/03	14,910		17.495	260,849		20,981	
VONTZ	12/10/03	15,000		16.565	248,468		21,782	
		54,910	**61 avg sold/day**		**$769,442**	**$860 avg total/day**	**20,148**	**avg holdings/day**
VONTZ	05/10/04	10,000	(895 day prior period)	18.363	183,625	(895 day prior period)	21,782	(895 day prior period)
VONTZ	08/09/04	10,000		25.046	250,455		23,134	
VONTZ	11/08/04	10,000		27.206	272,055		23,134	
VONTZ	04/25/05	2,279		28.000	63,812		23,845	
		32,279	**36 avg sold/day** (895 day class period)		**$769,947**	**$860 avg total/day** (895 day class period)	**22,974**	**avg holdings/day** (895 day class period)

Filer	Trans. Date	Shares		Price	Total		Holdings	
HIGGINS	04/01/02	2,000		9.610	19,220		74,799	
HIGGINS	06/05/02	3,000		12.690	38,070		75,745	
HIGGINS	08/01/02	4,000		10.660	42,640		71,745	
HIGGINS	10/01/02	5,000		9.280	46,400		66,745	
HIGGINS	12/02/02	6,000		12.116	72,696		62,755	
HIGGINS	02/03/03	7,000		12.950	90,650		55,755	
HIGGINS	02/20/03	5,000		15.000	75,000		66,089	
HIGGINS	02/20/03	6,095		15.160	92,400		n/a	
HIGGINS	03/17/03	7,000		16.080	112,560		59,089	
HIGGINS	04/07/03	8,000		17.500	140,000		51,089	
HIGGINS	09/03/03	5,119		18.320	93,780		67,865	
HIGGINS	10/14/03	10,000		19.000	190,000		57,864	
HIGGINS	11/28/03	2,184		10.302	22,500		60,048	
HIGGINS	01/20/04	15,000		20.054	300,816		45,048	
HIGGINS	01/21/04	10,000		22.001	220,008		45,048	
		95,398	**107 avg sold/day**		**$1,556,740**	**$1,739 avg total/day**	**61,406**	**avg holdings/day**
HIGGINS	02/09/04	15,000	(895 day prior period)	25.198	377,970	(895 day prior period)	45,049	(895 day prior period)
HIGGINS	02/20/04	5,809		21.280	123,616		66,197	
HIGGINS	03/12/04	5,000		22.364	111,819		81,195	
HIGGINS	06/15/04	10,000		20.774	207,739		73,470	
HIGGINS	07/30/04	15,000		27.500	412,500		73,470	
HIGGINS	08/02/04	15,000		27.398	410,967		58,470	
HIGGINS	08/02/04	4,554		27.630	125,827		83,916	
HIGGINS	11/01/04	7,500		26.622	199,663		76,416	
HIGGINS	11/10/04	5,000		29.169	145,845		76,416	
HIGGINS	01/14/05	12,500		22.760	284,500		77,297	
HIGGINS	03/15/05	4,000		27.950	111,800		77,297	
HIGGINS	04/19/05	5,000		29.000	145,000		77,297	
HIGGINS	05/31/05	1,154		18.403	21,237		78,451	
HIGGINS	06/10/05	10,000		20.707	207,073		68,451	
HIGGINS	08/22/05	15,000		17.729	265,940		68,451	
		130,517	**146 avg sold/day** (895 day class period)		**$3,151,494**	**$3,521 avg total/day** (895 day class period)	**72,123**	**avg holdings/day** (895 day class period)

Filer	Trans. Date	Shares		Price	Total		Holdings	
WIGGANS	03/01/02	15,000		10.300	154,500		174,759	
WIGGANS	05/01/02	15,000		11.640	174,600		n/a	
WIGGANS	08/01/02	15,000		10.470	157,050		180,968	
WIGGANS	11/29/02	1,752		4.196	7,351		180,220	
WIGGANS	12/11/02	7,000		n/a	n/a		173,220	
WIGGANS	03/10/03	15,000		14.660	219,900		169,720	
WIGGANS	04/30/03	15,000		16.750	251,250		179,220	
WIGGANS	05/06/03	350		0.000	n/a		204,346	
WIGGANS	07/31/03	15,000		18.010	270,150		202,559	
WIGGANS	09/08/03	5,000		0.000	n/a		197,559	
WIGGANS	10/31/03	15,000		17.824	267,357		169,083	
WIGGANS	11/28/03	713		10.302	7,345		169,796	
WIGGANS	01/07/04	2,000		n/a	n/a		167,796	
		121,815	**136 avg sold/day**		**$1,509,504**	**$1,687 avg total/day**	**180,771**	**avg holdings/day**
WIGGANS	02/02/04	15,000	(895 day prior period)	21.924	328,856	(895 day prior period)	165,796	(895 day prior period)
WIGGANS	02/17/04	6,880		21.400	147,232		210,001	
WIGGANS	03/10/04	12,000		22.095	265,144		207,001	
WIGGANS	03/10/04	500		22.095	11,048		14,486	
WIGGANS	05/10/04	500		18.477	9,239		13,986	
WIGGANS	05/10/04	12,000		18.477	221,725		197,001	
WIGGANS	08/02/04	1,500		0.000	n/a		196,244	
WIGGANS	08/09/04	12,000		25.046	300,557		184,244	
WIGGANS	08/09/04	500		25.046	12,523		13,986	
WIGGANS	08/10/04	3,500		0.000	n/a		180,744	
WIGGANS	11/08/04	12,000		27.213	326,556		168,744	
WIGGANS	11/08/04	500		27.213	13,607		12,986	
WIGGANS	02/07/05	500		23.460	11,730		12,486	
WIGGANS	02/07/05	12,000		23.460	281,515		157,492	
WIGGANS	03/14/05	30,000		27.710	831,300		157,492	
WIGGANS	03/15/05	2,000		n/a	n/a		155,492	
WIGGANS	04/21/05	1,500		n/a	n/a		153,992	
WIGGANS	05/10/05	500		n/a	n/a		153,492	
WIGGANS	07/01/05	20,000		17.431	348,616		146,066	
WIGGANS	08/01/05	20,000		18.530	370,596		134,066	
WIGGANS	09/01/05	20,000		19.077	381,544		126,066	
WIGGANS	11/15/05	4,000		13.200	52,800		124,066	
WIGGANS	12/15/05	4,000		14.856	59,425		122,566	
WIGGANS	01/13/06	4,000		14.544	58,177		120,566	
WIGGANS	03/01/06	4,000		16.062	64,246		258,996	
WIGGANS	06/26/06	5,900		n/a	n/a		266,233	
		205,280	**229 avg sold/day** (895 day class period)		**$4,096,434**	**$4,577 avg total/day** (895 day class period)	**140,550**	**avg holdings/day** (895 day class period)

Source: Vickers Stock Research

329. The transactions summarized above represent sales of Connetics stock by Defendants Wiggans and Higgins that are unusual in scope and timing because, among other things:

(i) In the two years prior to the Class Period, Defendant Wiggans averaged sales of $1,687 in Connetics stock per day. During the Class Period, Defedant Wiggans sold $4,577 in Connetics stock per day. This windfall profit from the sale of artificially inflated shares during the Class Period is nearly twice the amount that Wiggans received in salary and bonuses during the Class Period (*i.e.*, $2,369,000).

(ii) In the two years prior to the Class Period, Defendant Higgins averaged sales of $1,739 in Connetics stock per day. During the Class Period, Defedant Higgins sold $3,521 in Connetics stock per day. This windfall profit from the sale of artificially inflated shares is

> almost three times the amount Higgins received in salary and bonuses during the Class Period (*i.e.*, 1,375,000).

330. Defendants' sales are also suspicious because Defendants entered into Rule 10b5-1 trading plans while in possession of material, undisclosed information during the Class Period. Defendant Higgins entered into 10b5-1 plans on March 5, 2004, September 9, 2004 and March 14, 2005. Defendant Wiggans entered into 10b5-1 plans on March 9, 2004, March 14, 2005, May 12, 2005 and September 20, 2005. Defendant Vontz entered into Rule 10b5-1 trading plans during the Class Period on March 9, 2004 and March 14, 2005.

331. Lead Plaintiff does not plead Krochmal made any sales during the Class Period. Krochmal did not join the Company until October 2003. The vast majority of Krochmal's shares owned during the Class Period were in the form of unexcercisable stock options that did not vest until May 23, 2006, and were "underwater" during all or part of the Class Period.

332. In addition, Defendants Yaroshinsky and Zak made approximately $680,000 and $900,000, respectively, by trading on material non-public information, as set forth above.

E. Additional Indicia Of Scienter

333. Salary and Bonus Compensations. Defendants Wiggans, Higgins, Vontz and Krochmal were motivated to misrepresent Connetics' true financial condition and the issues with Velac in order to continue receiving their lucrative salaries and bonuses. Throughout the Class Period, Defendants Wiggans, Higgins, Vontz and Krochmal received millions of dollars in compensation in the form of base salaries, bonuses and option grants. The table below summarizes the base salary and bonus compensation granted to these Defendants through the Class Period.

	2004		2005		2006	
Name	**Salary**	**Bonus**	**Salary**	**Bonus**	**Salary**	**Total**
Wiggans	$514,000	$425,000	$530,000	$325,000	$575,000	$2,369,000
Vontz	$353,000	$233,000	$381,000	$190,000	$422,000	$1,579,000
Higgins	$315,000	$208,000	$325,000	$167,000	$360,000	$1,375,000
Krochmal	$375,000	$192,000	$386,000	$154,000	$400,000	$1,507,000

334. As Connetics disclosed, Defendants Wiggans, Higgins, Vontz and Krochmal received bonuses based on "the annual performance" of Connetics throughout the Class Period. (2006 Proxy at 18.) The amounts of the bonuses could range between zero and 60 percent of their base salary, depending on Connetics' success in achieving goals such as enhancing revenue and earnings per share, achieving certain product development goals (such as filing NDA's), and share price.

335. Stock Option Grants. Connetics awarded Defendants Wiggans, Higgins, Vontz and Krochmal millions of dollars in stock options during the Class Period. The options became exercisable at a rate of 25% of the shares at the end of the first twelve month period following the grant and monthly thereafter until the fourth anniversary of the grant. The following chart represents the number of stock options granted to these Defendants in fiscal years 2005 and 2004.

Fiscal 2005			
Name	Options Granted	Percentage (Of Options Granted to Employees in 2005)	Estimated Value* (As reported by Connetics)
Wiggans	135,000	7.8%	$5,023,875
Vontz	90,000	5.2%	$3,349,250
Higgins	81,000	4.7%	$3,014,325
Krochmal	45,000	2.6%	$1,674,625

Fiscal 2004			
Name	Options Granted	Percentage (Of Options Granted to Employees in 2005)	Estimated Value* (As reported by Connetics)
Wiggans	200,000	11.3%	$5,753,410
Vontz	112,000	6.3%	$3,221,910
Higgins	90,000	5.1%	$2,589,035
Krochmal	45,000	1.4%%	$719,176

*Estimated value assumes 10% stock price appreciation over option term and represents gains net of exercise price.

336. In the aggregate, this group of Defendants received 798,000 stock options during the Class Period, with an estimated potential value of more than **$25 million**. These Defendants were motivated to perpetrate the fraudulent scheme described herein in order to artificially inflate the value of Connetics' stock and increase the value of their stock options.

337. Moreover, these lucrative equity awards were granted primarily based on the Company's achievement of many of the same objectives that these Defendants manipulated during the Class Period. For instance, Connetics disclosed that these "incentive awards" were determined by certain "performance goals" such as:

(i) Revenue;

(ii) Earnings per Share;

(iii) Product Launches;

(iv) Timely NDA and other regulatory filings;

(v) Achievement of various product development goals; and

(vi) Achievement of other goals such as "earnings; earnings growth . . . operating income . . . stock price."

(2006 Proxy at A-2.) Thus, these Defendants had a uniquely strong incentive to commit the financial fraud described herein in order to inflate the Company's revenue, Earnings per Share, earnings, earnings growth, operating income and stock price so that they could receive millions of dollars in valuable stock options and other compensation. Likewise, these Defendants had direct financial incentives to conceal the significant issues with Velac so that the Company could complete the NDA and other regulatory filings, which would result in the seeming achievement of "performance goals" that would result in lucrative stock grants and other compensation for these Defendants.

338. Direct Equity Interests. In addition to the significant stock options that were granted to them during the Class Period and would vest over a period of years, during the Class Period, Defendants Wiggans, Higgins, Vontz and Krochmal owned millions of additional shares of Connetics' common stock valued at tens of millions of dollars. These Defendants knew that, if the truth about Connetics were revealed, the value of these stock holdings would plummet, and severely reduce their personal net worth. The following chart sets forth the stock owned by these Defendants as of March 24, 2006 (as indicated in the Company's 2006 Proxy statement):

Stock Ownership (As of March 24, 2006)		
Name	**Shares Vesting**	**Estimated Value (at 3/24/06 prices)**
Wiggans	281,972	$4,793,524
Vontz	128,820	$2,189,940
Higgins	135,369	$2,301,273
Krochmal	60,860	$1,034,620

339. In the aggregate, this group of Defendants owned 607,021 shares of Connetics stock as of March 24, 2006, with value on that date of more than $10 million. These Defendants were motivated to perpetrate the fraudulent scheme described herein in order to create and maintain the artificial inflation in the Connetics common stock that represented the vast majority of these Defendants' personal net worth.

340. Significant Options Vesting at End of Class Period. Additional motivation for these Defendants to perpetrate the fraudulent scheme throughout the Class Period is the fact that each of them owned significant options that had been granted prior to and during the Class Period, but would not vest until near the end of the Class Period. The following chart sets forth the number of options that were scheduled to vest for each of these Defendants on or about May 23, 2006:

Stock Ownership (As of May 23, 2006)		
Name	**Shares Vesting**	**Estimated Value (at 3/24/06 prices)**
Wiggans	1,244,275	$21,152,675
Vontz	608,887	$10,351,079
Higgins	468,256	$7,960,352
Krochmal	153,333	$2,606,661

341. In the aggregate, a staggering 2,943,638 shares (a nearly 500% increase over the amount they currently owned) were about to vest for these Defendants near the end of the Class Period. These shares had a value of more than **$41.9 million** as of March 24, 2006.

342. Share Repurchase Program. The Insider Defendants' scienter is further demonstrated by the significant number of shares that the Insider Defendants caused Connetics to repurchase during the Class Period. In addition to the significant share repurchase program that was funded by a portion of the proceeds Connetics received from the Private Placement, in October 2005 Connetics authorized the repurchase of up to $50 million in additional common stock. By December 31, 2005, the Company had repurchased 1.8 million shares at a cost of $24.4 million and repurchased another 143,000 shares by March 31, 2006. These repurchases, which were designed and implemented by Wiggans, Higgins and Vontz, increased the value of the Insider Defendants' equity holdings and options at no cost to themselves.

VIII. LOSS CAUSATION

343. Throughout the Class Period, as detailed above, the prices of the Company's securities were artificially inflated as a direct result of Defendants' misrepresentations and omissions regarding the Company. When the truth about the Company was partially revealed to the market at various times including, but not limited to, April and June 2005, May 2006 and July 2006, the inflation that had been caused by Defendants' misrepresentations and omissions was eliminated from the price of the Company's securities, causing significant damages to Lead Plaintiff and the other Class members. As set forth in detail above, Connetics' securities consistently reacted to information in the market place, for instance:

(i) On April 27, 2005, Connetics' common stock closed at $22.30, down $5.27 from its April 26, 2005 high of $28.24, a 19% decrease, on heavy trading volume. Between April 20, 2005 and April 27, 2005, Connetics' bond prices dropped $22.26 from a price of $133.91 on April 20, 2005 to $111.65 on April 27, 2005, a decrease of approximately 17%. These drops were attributable to the partial disclosure of the truth concerning Velac, as described herein at ¶¶116-126.

(ii) On Monday, June 13, 2005, Connetics' common stock closed at $15.13, down $5.72 from its Friday, June 10, 2005 high of $20.85, a 27% decrease, on heavy trading. Between June 6, 2005 and June 13, 2005, Connetics' bond prices fell $14.53 from $110.61 to $96.08, a decrease of approximately 13%. These drops were attributable to the partial disclosure of the truth concerning Velac, as described herein at ¶¶127-132.

(ii) On May 3, 2006, the Company's trading volume was approximately 1.8 million shares – an increase of over 700% from May 2, 2006 when the trading volume was only 242,800 shares. The stock declined from a close on May 2, 2006 of $15.27, to a close on May 3, 2006 of $13.76, a decrease of approximately 10%. Connetics issued a press release after the close of

the market on May 3, 2006. Based on trading volume and price decline, the information in the press release, leaked to the market prior to the close of trading on May 3. On May 3, 2006, Connetics' bonds traded at $92.94 down $2.57 from their trading price on May 2, 2006 of $95.51, a decrease of approximately 3%. These drops were attributable to the partial disclosure of the truth concerning Defendants' accounting manipulations, as described herein at ¶¶177-178, 298-306.

(iii) On May 23, 2006, the price of Connetics' common stock traded as low as $12.51 per share, down $0.75 from its May 22, 2006 closing price of $13.26 per share, a decrease of approximately 6%. These drops were attributable to the partial disclosure of the truth concerning Defendants' accounting manipulations, as described herein at ¶181.

(iv) On July 10, 2006 the price of Connetics' common stock closed at $7.76 down $3.93 from its closing price on July 7, 2006 (the immediately preceding trading day) of $11.69 per share, a decrease of approximately 34% on heavy trading volume. By July 24, 2006, Connetics' bond prices fell to $95.62, a decrease of approximately 30% from their Class Period high. These drops were attributable to the partial disclosure of the truth concerning Defendants' accounting manipulations, as described herein at ¶¶182-184.

344. The declines in the Company's securities prices following these revelations, and the resulting damages suffered by Lead Plaintiff and the other members of the Class are directly attributable to the market's reaction to the disclosure of information that had previously been misrepresented or concealed by Defendants, and to the market's adjustment of the Company's securities prices to reflect the newly emerging truth about the Company's condition. Had Lead Plaintiff and the other members of the Class known of the material adverse information not disclosed by Defendants named herein, or been aware of the truth behind these Defendants' material misstatements, they would not have purchased Connetics securities at artificially inflated prices.

IX. INAPPLICABILITY OF STATUTORY SAFE HARBOR

345. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false or misleading statements pleaded in this Complaint. The statements alleged to be false or misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false or misleading may be characterized as forward-looking, they were not adequately identified as forward-looking statements when made, and there were no meaningful cautionary statements identifying important facts that could cause actual results to differ materially from those in the

purportedly forward-looking statements. To the extent that the statutory safe harbor is intended to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, Defendants had actual knowledge that the particular forward-looking statement was materially false or misleading. In addition, to the extent any of the statements set forth above were accurate when made, they became inaccurate or misleading because of subsequent events, and Defendants failed to update those statements which later became inaccurate.

X. CLASS ACTION ALLEGATIONS

346. Oklahoma Teachers brings this action on its own behalf and as a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of all persons or entities (the "Class") who acquired the securities of Connetics during the period from January 27, 2004, through July 9, 2006, inclusive, and who suffered damages as a result. Excluded from the Class are: (i) the Defendants; (ii) members of the family of each individual Defendant; (iii) any person who was an officer or director of Connetics during the Class Period; (iv) any person who is named as a defendant in any U.S. Government or state criminal or civil proceeding relating to Connetics; (v) any firm, trust, corporation, officer, or other entity in which any Defendant has a controlling interest; and (vi) the legal representatives, agents, affiliates, heirs, successors-in-interest or assigns of any such excluded party.

347. The Class is so numerous that joinder of all Class members is impracticable. Connetics common stock was actively traded on the NASDAQ, an efficient market, throughout the Class Period. The market for Connetics' convertible bonds was also an efficient market as they traded on the PORTAL exchange and other national exchanges during the Class Period. While the exact number of Class members can only be determined by appropriate discovery, Lead Plaintiff believes that Class members number in the tens of thousands. During the Class Period there were approximately 33.5 million shares of Connetics' common stock in the public float, and in excess of $200 million face value of Connetics' convertible bonds. Based upon the volume of trading of Connetics' common stock and bonds during the Class Period, it is believed that tens of thousands of investors purchased Connetics common stock and bonds during the

Class Period, rendering joinder of all such purchasers impracticable.

348. Lead Plaintiff's claims are typical of the claims of the members of the Class. Lead Plaintiff and all Class members sustained damages as a result of the wrongful conduct complained of herein.

349. Lead Plaintiff will fairly and adequately protect the interests of the Class members and has retained Court-appointed counsel competent and experienced in class action and securities litigation. Lead Plaintiff has no interests that are contrary to or in conflict with those of the Class members that Lead Plaintiff seeks to represent.

350. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it virtually impossible for the Class members individually to seek redress for the wrongful conduct alleged herein.

351. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:

(i) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(ii) whether documents, including the Company's SEC filings, press releases and public statements made by Defendants during the Class Period contained misstatements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(iii) whether Defendants acted with the requisite state of mind in omitting and/or misrepresenting material facts in the documents filed with the SEC, press releases and public statements;

(iv) whether the market prices of Connetics' common stock and bonds during the Class Period were artificially inflated due to the material misrepresentations complained of herein; and

(v) whether the Class members have sustained damages and, if so, the appropriate measure thereof.

352. Lead Plaintiff knows of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.

353. The names and addresses of the record owners of Connetics' securities purchased during the Class Period are obtainable from information in the possession of the Company's transfer agent(s) and the Company's underwriters. Notice can be provided to the record owners of Connetics stock and bonds via first class mail using techniques and a form of notice similar to those customarily used in securities class actions.

XI. PRESUMPTION OF RELIANCE

354. The market for the Company's securities was, at all times, an efficient market that promptly digested current information with respect to the Company from all publicly-available sources and reflected such information in the prices of the Company's securities. Throughout the Class Period:

(a) Connetics stock was actively traded on the NASDAQ;

(b) The market price of Connetics' securities reacted promptly to the dissemination of public information regarding the Company;

(c) Securities analysts followed and published research reports regarding Connetics that were publicly available to investors;

(d) The average weekly trading volume for Connetics stock during the Class Period was approximately 10 percent of average total outstanding shares; and

(e) The Company's market capitalization was approximately $890 million during the Class Period.

355. Throughout the Class Period, the Company was consistently followed by securities analysts as well as the business press. During this period, Connetics and certain Defendants continued to pump materially false information into the marketplace regarding the financial condition of the Company. This information was promptly reviewed and analyzed by the ratings agencies, analysts and institutional investors; assimilated into the ratings agencies' ratings for the convertible notes and into analysts and investors' analysis of the creditworthiness and the probability of default on the notes; and reflected in the market price of the notes.

356. In addition, following the Private Placement, a secondary market developed for the Company's convertible notes. Because the notes were convertible under certain conditions to shares of the Company's common stock, the notes reacted to the same information and market

disclosures that impacted the trading of Connetics' common stock. The secondary market for the notes broadened with the issuance of the Bond Registration Statement, after which the Registered Bonds became freely tradeable in the public markets. At all relevant times, major brokerage houses served as market makers and/or dealers in the Registered Bonds, and information regarding the prices at which the Registered Bonds were trading was publicly available through various pricing services.

357. As a result of the misconduct alleged herein (including Defendants' misstatements and omissions), the market for Connetics securities was artificially inflated. Under such circumstances, the presumption of reliance available under the "fraud-on-the-market" theory applies.

358. Lead Plaintiff and the other Class members justifiably relied on the integrity of the market price for the Company's securities and were substantially damaged as a direct and proximate result of their purchases of Connetics securities at artificially inflated prices and the subsequent decline in the price of those securities when the truth was disclosed.

359. Had Lead Plaintiff and the other members of the Class known of the material adverse information not disclosed by the Defendants, or been aware of the truth behind the Defendants' material misstatements, they would not have purchased Connetics securities at artificially inflated prices.

XII. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT

COUNT ONE
For Violations Of Section 10(b) Of The Exchange Act And Rule 10b-5 Promulgated Thereunder Against Defendants Connetics, Wiggans, Higgins, Vontz, Krochmal, Yaroshinsky and Zak

360. Lead Plaintiff repeats and realleges each of the allegations set forth above as if fully set forth herein. This Claim is brought pursuant to Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder, on behalf of Lead Plaintiff and all other members of the Class, against Defendants Connetics, Wiggans, Higgins, Vontz, Krochmal, Yaroshinsky and Zak.

361. As alleged herein, throughout the Class Period, the Defendants, individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce, the mails and the facilities of a national securities exchange, employed devices,

schemes and artifices to defraud, made untrue statements of material fact and/or omitted to state material facts necessary to make statements made not misleading, and engaged in acts, practices and a course of business which operated as a fraud and deceit upon Class members, in violation of Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder.

362. Connetics' and the Insider Defendants' false and misleading statements and omissions were made with scienter and were intended to and did, as alleged herein, (i) deceive the investing public, including Lead Plaintiff and the other members of the Class; (ii) artificially create, inflate and maintain the market for and market price of the Company's securities; and (iii) cause Lead Plaintiff and the other members of the Class to purchase the Company's securities at inflated prices.

363. Connetics and the Insider Defendants were individually and collectively responsible for making the statements and omissions alleged herein, by virtue of having prepared, approved, signed, and/or disseminated documents which contained untrue statements of material fact and/or omitted facts necessary to make the statements therein not misleading and/or making direct statements to the investing public on the conference calls detailed herein.

364. As described herein, Connetics and the Insider Defendants made the false statements and omissions knowingly and intentionally, or in such an extremely reckless manner as to constitute willful deceit and fraud upon Lead Plaintiff and other members of the Class who purchased Connetics securities during the Class Period. Throughout the Class Period, Connetics and the Insider Defendants had a duty to disclose new information that came to their attention, which rendered their prior statements to the market materially false and misleading.

365. Connetics and the Insider Defendants' false statements and omissions were made in connection with the purchase or sale of the Company's securities.

366. In ignorance of the false and misleading nature of Connetics and the Insider Defendants' statements and omissions, and relying directly or indirectly on those statements and/or upon the integrity of the market price for Connetics securities, Lead Plaintiff and the other members of the Class purchased Connetics' securities at artificially inflated prices during the Class Period. But for the fraud, they would not have purchased the securities at artificially

inflated prices.

367. The market price for Connetics' securities declined materially upon the public disclosure of the facts that had previously been misrepresented or omitted by Connetics and the Insider Defendants, as described above.

368. During the Class Period, Defendants were privy to non-public information concerning the Company and had a duty to refrain from trading in Connetics securities while in possession of this material, adverse, non-public information.

369. Defendants did not refrain from such trading but rather profited by trading on the basis of the non-public information known to them. By trading in Connetics securities while in possession of this material, adverse, non-public information, as is detailed herein, Defendants violated Section 10(b) and Rule 10b-5.

370. At the same time that these Defendants traded in Connetics securities, Lead Plaintiff and other plaintiffs who are members of the Class traded contemporaneously with Defendants in ignorance of the material, adverse, non-public information known to Defendants.

371. Lead Plaintiffs and the other members of the Class were substantially damaged as a direct and proximate result of their purchases of Connetics' securities at artificially inflated prices and the subsequent decline in the price of those securities when the truth was disclosed.

372. This claim was brought within two years after discovery of this fraud and within five years of the making of the statements alleged herein to be materially false and misleading.

373. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder and are liable to Lead Plaintiff and the members of the Class, each of whom has been damaged as a result of such violation.

COUNT TWO
For Violations Of Section 20(a) Of The Exchange Act Against Defendants Wiggans, Higgins And Vontz

374. Lead Plaintiff repeats and realleges each of the allegations set forth above as if fully set forth herein. This Claim is brought pursuant to Section 20(a) of the Exchange Act against Defendants Wiggans, Higgins and Vontz (collectively, the "Section 20(a) Defendants"), on behalf of Lead Plaintiff and all members of the Class who purchased Connetics' securities

during the Class Period.

375. As alleged herein, Connetics is liable to Lead Plaintiff and the members of the Class who purchased Connetics' securities based on the materially false and misleading statements and omissions set forth above, pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

376. Throughout the Class Period, the Section 20(a) Defendants were controlling persons of Connetics within the meaning of Section 20(a) of the Exchange Act, and particularly and culpable participants in the Connetics' fraud, as detailed herein.

377. Each of these Defendants exercised control over Connetics during the Class Period by virtue of, among other things, their executive positions with the Company, the key roles each played in the Company's management, and their direct involvement in its day-to-day operations, including its financial reporting and accounting functions.

378. In addition to the allegations set forth above, the following allegations demonstrate the Section 20(a) Defendants' control over Connetics during the Class Period. Defendant Wiggans was a controlling person of Connetics throughout the Class Period as demonstrated by the facts alleged herein, including:

(i) Wiggans served as President of Connetics from July 1994 to February 2005, and as Chief Executive Officer and a director throughout the Class Period.

(ii) Beginning in January 2006 Wiggans served also as the Chairman of the Board of Directors.

(iii) Wiggans, along with Higgins, was ultimately responsible for ensuring that the internal disclosure and accounting procedures were effective and required no changes. Consistent with that responsibility, he signed each of Connetics' Form 10-Ks and 10-Qs throughout the Class Period and the Registration Statement. Pursuant to Sections 302 and 906 of Sarbanes Oxley, Wiggans certified the accuracy of Connetics' Form 10-Ks and 10-Qs and the effectiveness of Connetics' disclosure and internal control procedures.

(iv) Throughout the Class Period, Wiggans also led each of Connetics' conference calls with analysts and investors, where he responded to questions relating to all aspects of Connetics' business, strategic direction, and financial performance.

(v) Wiggans was a member of Connetics' Management Executive Committee.

379. Defendant Higgins was a controlling person of Connetics throughout the Class Period as demonstrated by the facts alleged herein, including:

(i) Higgins served as the Executive Vice President, Finance and Corporate Development and Chief Financial Officer throughout the Class Period.

(ii) From January 2002 through the end of the Class Period, Higgins served as the Executive Vice President, Finance and Administration.

(iii) Higgins was ultimately responsible with Wiggans for ensuring that the internal disclosure and accounting procedures were effective and required no changes. Consistent with that responsibility, he signed each of Connetics' Form 10-Ks and 10-Qs throughout the Class Period and the Registration Statement. Pursuant to Sections 302 and 906 of Sarbanes Oxley, Higgins certified the accuracy of Connetics' Form 10-Ks and 10-Qs and the effectiveness of Connetics' disclosure and internal control procedures.

(iv) Throughout the Class Period, Higgins also participated in each of Connetics' conference calls with analysts and investors, where he responded to questions relating to all aspects of Connetics' business, strategic direction, and financial performance.

(v) Higgins was a member of Connetics' Management Executive Committee.

380. Defendant Vontz was a controlling person of Connetics throughout the Class Period as demonstrated by the facts alleged herein, including:

(i) Vontz served as President and Chief Operating Officer of Connetics throughout the Class Period.

(ii) He was appointed President in February 2005 (succeeding Wiggans).

(iii) Vontz participated in each of Connetics' conference calls with analysts and investors throughout the Class Period, where he responded to questions relating to all aspects of Connetics' business, strategic direction, and financial performance.

(iv) Vontz was a member of Connetics' Management Executive Committee.

381. Given their individual and collective responsibilities for managing Connetics throughout the Class Period, the Section 20(a) Defendants were regularly presented to the market as the individuals who were responsible for Connetics' day-to-day business and operations, as well as the Company's strategic direction. These Defendants accepted responsibility for presenting quarterly and annual results, setting guidance for future periods and assuring the market about the state of, and prospects for, product development. No one else at Connetics exercised that degree of responsibility for, or control over, the Company's activities and public statements.

382. As a result of the false and misleading statements and omissions alleged herein, the market price of Connetics securities was artificially inflated during the Class Period. Under such circumstances, the presumption of reliance available under the "fraud on the market" theory applies, as more particularly set forth above. Lead Plaintiff and the members of the Class relied upon either the integrity of the market or upon the statements and reports of the Defendants in purchasing Connetics securities at artificially inflated prices.

383. As a direct and proximate result of the wrongful conduct alleged herein, Lead Plaintiff and other members of the Class suffered damages in connection with their purchases of Connetics' securities. Had Lead Plaintiff and the other members of the Class known of the material adverse information not disclosed by Defendants, or been aware of the truth behind their material misstatements, they would not have purchased the securities at artificially inflated prices.

384. This claim was brought within two years after the discovery of this fraud and within five years of the making of the statements alleged herein to be materially false and misleading.

385. By virtue of the foregoing, each of the Section 20(a) Defendants are liable to Lead Plaintiff and the members of the Class, each of whom has been damaged as a result of Connetics' underlying violations.

COUNT THREE
For Violations Of Section 20A Of The Exchange Act
Against Defendants Wiggans, Higgins, Vontz, Yaroshinsky And Zak

386. Lead Plaintiff repeats and realleges each of the allegations set forth above as if fully set forth herein.

387. This Claim is brought pursuant to Section 20A of the Exchange Act against Defendants Wiggans, Higgins, Vontz, Yaroshinsky and Zak (collectively, the "Section 20A Defendants") on behalf of all members of the Class damaged by the Section 20A Defendants' insider trading during the Class Period.

388. The Section 20A Defendants, were in possession of material non-public information about Connetics. As alleged above, the Section 20A Defendants took advantage of the material non-public information regarding the likelihood the FDA would approve Velac and

concerning Connetics' improper accounting to make hundreds of thousands of dollars in insider trading profits during the Class Period. These transactions were made while the Section 20A Defendants possessed material non-public information.

389. In violation of his fiduciary duty to Connetics, and for his direct or indirect personal benefit, Defendant Yaroshinsky communicated material, non-pubic information concerning Velac to Defendant Zak, who could have reasonably been expected to use this information to his advantage prior to the Company's June 13, 2005 announcement that the FDA had not approved Velac Gel.

390. Defendant Zak conducted the securities transactions in Connetics securities as described herein while in possession of material, non-public information that Defendant Zak knew, or was reckless in not knowing, that Defendant Yaroshinsky had conveyed to him in breach of Defendant Yaroshinsky's fiduciary duty of trust and confidence to Connetics.

391. The Section 20A Defendants' transactions in Connetics' securities were made contemporaneously with Lead Plaintiff's and Class members' purchases of Connetics' securities during the Class Period. For instance, Lead Plaintiff purchased approximately 92,000 shares of Connetics common stock on April 18, 2005 and April 19, 2005. Defendants Higgins sold 5,000 shares on April 19, 2005, and Defendants Yaroshinsky and Zak traded on inside information throughout the period between April 14 and April 26, during which period Connetics had imposed a ban on trading in Connetics securities as set forth in the SEC Complaint ¶24 and herein.

392. All members of the Class who purchased shares of Connetics' securities contemporaneously with sales by the Section 20A Defendants (i) have suffered damages because, in reliance on the integrity of the market, they paid artificially inflated prices as a result of the violations of Section 10(b) and 20(a) of the Exchange Act as alleged herein; and (ii) would not have purchased the securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by the Defendants false and misleading statements and concealment. At the time of the purchases of the securities members of the Class, the fair

and true market value of the securities was substantially less than the price paid by these Class members.

XIII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for relief and judgment as follows:

A. Declaring this action to be a proper class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein;

B. Awarding Lead Plaintiff and the Class compensatory damages and/or rescission;

C. Awarding Lead Plaintiff and the Class pre-judgment and post-judgment interest, as well as reasonable attorneys' fees, expert witness fees and other costs;

D. Awarding Lead Plaintiff and the Class the fees and expenses incurred in this action, including expert witness fees and attorneys fees; and

E. Awarding such other relief as this Court may deem just and proper.

XIV. JURY TRIAL DEMAND

Lead Plaintiff hereby demands a trial by jury in this action of all issues so triable.

Dated: March 14, 2008

Respectfully submitted,

BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP

/s/ David R. Stickney
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Attorneys for Lead Plaintiff Teachers' Retirement System of Oklahoma and Lead Counsel to the Class

CERTIFICATE OF SERVICE

I, Kristina L. Sousek, do hereby certify that on this 14th day of March, 2008, a true and correct copy of the foregoing

SECOND AMENDED CONSOLIDATED
CLASS ACTION COMPLAINT FOR VIOLATIONS
OF THE FEDERAL SECURITIES LAWS

was filed electronically. Those attorneys who are registered with the Electronic Case Filing ("ECF") System may access this filing through the Court's system, and notice of this filing will be sent to the parties by operation of the Court's ECF System. Attorneys not registered with the Court's ECF system will be duly and properly served via Federal Express or U.S. Mail (as indicated on the attached Service List), in accordance with the Federal Rules of Civil Procedure and the Court's Local Rules.

I further declare that, pursuant to Civil L.R. 23-2, on this date I served copies of the above documents on the Securities Class Action Clearinghouse by electronic mail through the following electronic mail address provided by the Securities Class Action Clearinghouse:

jcarlos@law.stanford.edu

/s/Kristina L. Sousek
Kristina L. Sousek

Service List

In re CONNETICS SECURITIES LITIGATION
Case No.: 07-02940

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